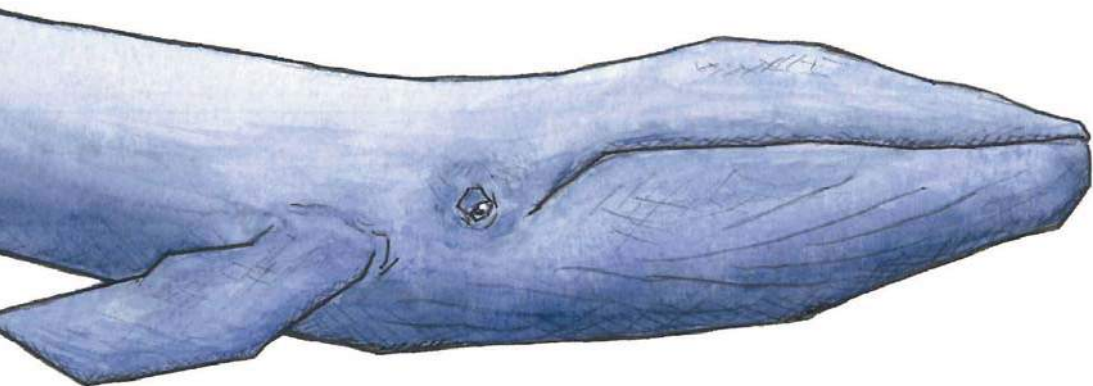


# PatientTIME

Participatory development and evaluation  
of a web-based, pre-visit communication tool  
for patients with malignant lymphoma

Inge van Bruinessen





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## Colofon

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ISBN: 987-94-6122-400-2

Lay-out: Doortje Saya

Cover design: Lydia Kapsenberg

This thesis is printed on FSC certified paper



The study presented in this thesis has been performed at NIVEL, Netherlands Institute for Health Services Research, Utrecht, The Netherlands. NIVEL participates in the Netherlands School of Primary Care Research (CaRe), acknowledged by the Royal Dutch Academy of Science (KNAW). Financial support for the studies in this thesis was provided by the Alpe d'HuZes programme of the Dutch Cancer Society. Financial support for printing this thesis was provided by NIVEL and Radboud university medical center.

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## Proefschrift

ter verkrijging van de graad van doctor  
aan de Radboud Universiteit Nijmegen  
op gezag van de rector magnificus prof. dr. J.H.J.M. van Krieken,  
volgens besluit van het college van decanen  
in het openbaar te verdedigen  
op woensdag 26 oktober 2016 om 14.30 uur precies

door

Inge Renske van Bruinessen

Geboren op 10 maart 1983  
te Oostburg

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# 1

## General introduction

*From the moment a person is diagnosed with cancer, his or her life changes dramatically. Both the disease and the treatment have a major impact on the person's emotional, psychological and physical well-being<sup>1-3</sup>. An important and difficult part of living with cancer concerns communication during hospital visits. These visits are important as they reveal if the treatment has been successful, whether the patient is in remission or cured, and set the stage for how to cope with life until the next hospital visit. Since how patients cope between follow-up visits partly depends on the information and support received during the visits, it is important for patients to get the most out of these visits and to enable patients the best one can<sup>\*</sup>.*

In 2009 a group of Dutch patients diagnosed with malignant lymphoma expressed their need for support in communication during medical encounters. Their request fitted the increased focus on shared decision-making and patient empowerment in health care. It also matched the urge to improve the medical dialogue in cancer care and to get a better insight in how patients can be supported in communicating effectively. These developments and the patients' request triggered the initiation of a patient-participatory project, described in this thesis.

## **1.1 Communication in health care**

Communication is considered an essential part of high quality patient care<sup>4 5</sup>. The interaction between professional and patient is the fundamental vehicle to exchange information. For the professional, effective information-exchange is necessary to manage and solve biomedical and psychosocial problems. For the patient it is important to 'know and understand', and the communication also serves a purpose in their need to 'feel known and understood'<sup>6</sup>. Indirectly the way communication unfolds has been linked to a range of patient outcomes such as satisfaction, treatment compliance, perceived quality of life and physical health<sup>7-11</sup>.

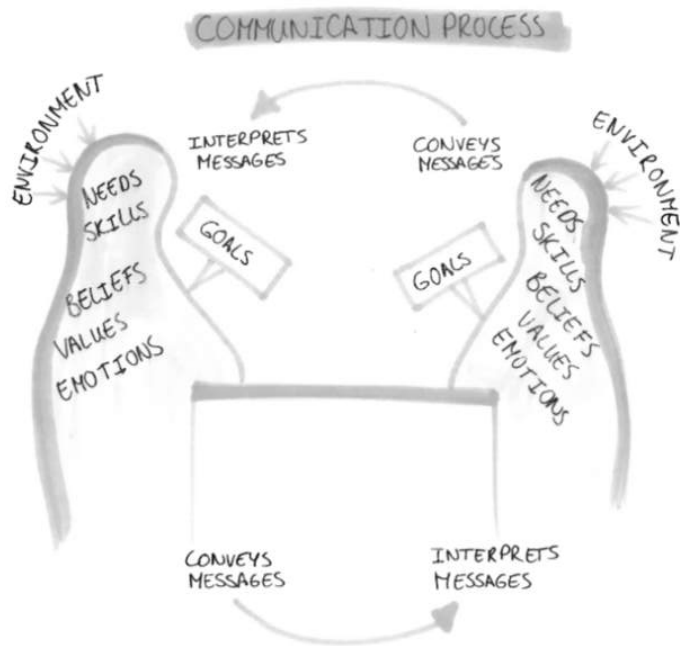
### **1.1.1 A dynamic stage that challenges its actors**

The communication process is influenced by the participants' goals, their attributes and external factors<sup>12</sup>; an ever-changing context (figure 1). In order to deliver good

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<sup>\*</sup> Derived from the research proposal written by Prof. dr. Sandra van Dulmen

care, the goals of both patient and professional need to be addressed. De Haes and Bensing proposed a model of medical communication in which they distinguish six goals; 1) fostering the relationship, 2) gathering information, 3) information provision, 4) decision-making, 5) enabling disease and treatment-related behaviour, and 6) responding to emotions<sup>4</sup>. Accomplishing these goals is of great importance to deliver good care. The attributes (or qualities) of the involved participants also determine the course of the interaction<sup>12</sup>. Attributes include needs, beliefs, values, skills and emotions and represent the internal factors that together make up an individual. They affect the content of the conversation and the way messages are formulated and received. Moreover, there is the variety of external factors that influence the communication process. These external factors can have a social, cultural, legal or physical nature and influence the goals and attributes of the professional and patient. The often complex nature of the medical dialogue and its dynamic stage challenge professionals and patients in achieving effective communication (figure 1).



**Figure 1** The communication process, derived from Feldman-Stewart et al. 2005<sup>12</sup>

### 1.1.2 Communication in cancer care

The challenges in communication may be explicitly evident in oncology care, where burdensome biomedical and psychosocial issues intertwine, and need to be discussed. In the initial phase of the diagnosis and primary treatment, patients are often overwhelmed and distressed during the clinical consultation<sup>13</sup>. At the same time, complex information needs to be exchanged about (e.g.) treatment options and managing side effects.

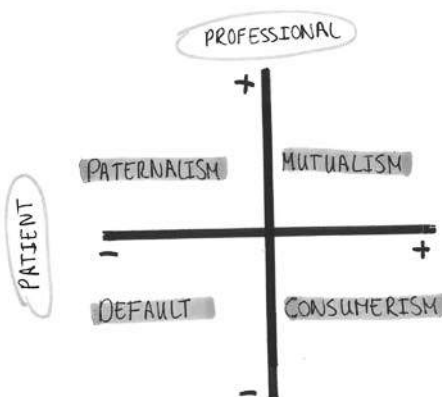
After primary treatment, other issues arise that influence the patient-professional interaction. Many patients have to deal with complications from treatment, long monitoring periods, (fear for) recurrence or second primary cancers, psychosocial issues and so on<sup>14</sup>. According to the biopsychosocial model, patients do not only need to communicate about these disease-specific aspects, they also look for emotional support, i.e. they need to be heard and taken seriously by an attentively listening health care provider<sup>6</sup>.

### 1.1.3 Modelling the medical dialogue

The medical dialogue is described by Roter in a model with four quadrants which are defined by the nature of the patient-professional relationship<sup>15</sup>. The different models vary in the level of control demonstrated by each participant (figure 2).

*Paternalism* describes the dominant role of the professional whereas the patient is merely passive. Conversely, *consumerism* describes an active, dominant patient combined with a passive role of the professional. When the power is balanced and there is shared control, the dialogue is defined as *mutualism*. *Default* describes the lack of control over the dialogue by both participants.

From an ethical and empirical background, a patient-centred communication style is more and more advocated. A shift from the traditional paternalistic communication style to a more mutual relationship requires an active role of the patient<sup>12, 15</sup>. In this context, patients are increasingly expected to be informed participants and to be able to make conscious decisions together with their health



**Figure 2** Patient-professional relationships, derived from Roter et al. 2000<sup>15</sup>

care provider<sup>16</sup>. In the Netherlands, the importance of a participatory role of the patient is also underlined at the governmental level<sup>17, 18</sup>.

## **1.2 Supporting patients in effective communication**

A variety of developments and trends has changed the traditional role of the patients during medical encounters. These developments have led to initiatives aiming to support patients in communication. The following paragraphs outline these developments and introduce activities aiming to support patients.

### **1.2.1 Why supporting patients?**

The health care professional and the patient influence each other during a consultation and they both determine the effectiveness of communication<sup>12</sup>. Professionals are responsible for facilitating the process and content of the medical communication. In the past decades, interest in research and educational programs in the field of communication training for professionals has increased<sup>19, 20</sup>. In the Netherlands, communication training has become an essential part in medical school.

But communication is a two-way interaction. The aforementioned emphasis on patient-centeredness requires active patient involvement and shared decision-making. Moreover, patients with severe conditions are often confronted with a large number of medical specialists and other health care professionals, who will not and cannot all be skilled communicators. Empowering these patients to become skilled communicators may therefore be highly effective.

In cancer care, many patients seem to prefer an active role during consultations<sup>21</sup>, but their conversational contribution in the consultation room is often limited<sup>22-25</sup>. This suggests a discrepancy between the patients' preferred and actual role<sup>21, 26, 27</sup>.

Patients experience barriers in medical communication and in playing their expected active role in clinical consultations. In a sample of 1314 chronic patients, of which a substantial portion diagnosed with cancer, 46% of the respondents reported barriers to participation and 39% were interested in communication support. Patients relate these barriers to the context (like the amount of time during a consultation), the professional (for example when (s)he keeps the conversation too general) and not in the least, to their own attributes (such as a lack of communication skills and interfering beliefs)<sup>28, 29</sup>. As a result, they continue to have unmet communication needs<sup>30</sup>.

It is known that patients tend to give cues, but often do not explicitly convey what is most important and most emotionally salient for them in consultation with a health care professional<sup>31</sup>. These (non)verbal hints to a hidden need or emotion often remain unnoticed by the professional<sup>32</sup>. A study among oncologists showed that professionals prefer to listen at and respond to certain disease cues over others<sup>33</sup>.

Cancer patients who achieve their preferred role are most satisfied with their consultation, whereas patients who are less active than desired are least satisfied<sup>34</sup>. Patients should therefore be supported to express their concerns and questions in a more direct and straightforward but effective way. Research reveals the potential benefit of supporting patients to overcome communication barriers<sup>35-40</sup>. Next to training professionals, this approach may be interesting in the attempt to improve doctor-patient communication.

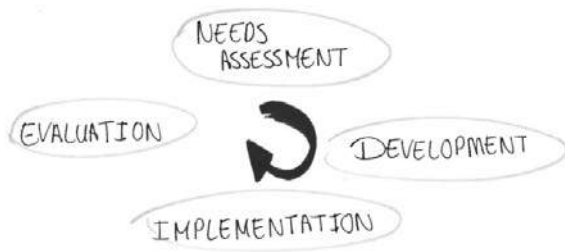
### **1.2.2 How to support patients?**

Epstein and Street (2007) have stressed the need for developing specific types of interventions to support cancer patients, such as in-person coaching, interactive computer programs, videos of role models, and question prompt sheets<sup>41</sup>. A review examining the characteristics of available patient-targeted communication supports in cancer care identified 30 unique interventions until mid-2010<sup>40</sup>. The majority of these interventions was delivered face-to-face, others were delivered in print or online. The interventions focussed merely on the initial treatment planning visits (instead of communication during treatment or follow-up consultations), were not often tailored to a specific type of cancer with the exception of breast cancer and few originated from non-English-speaking or European countries.

### **1.2.3 Intervention development and active patient participation**

Developing a patient-targeted intervention is not a domain on its own. In the practice of health education, four activities are distinguished; conducting a needs assessment, develop an intervention, implementation and evaluating the effectiveness<sup>42</sup> (figure 3). The process and outcomes of needs assessments and evaluations of interventions are well-documented domains. The development and design of an intervention for the medical context and its implementation is rarely discussed in detail<sup>42</sup>, let alone the way patients participated in this process. Patient participation in intervention development is frequently referred to. The potential benefits are widely accepted and there is a clear urge for more patient

involvement<sup>43</sup>. In practice, however, the actual operationalization, that is, how and when (seriously ill) patients are involved, is rarely reported<sup>44, 45</sup>. It often seems a more symbolic statement or it is used to describe the participation of patients when evaluating the effectiveness of an intervention.



**Figure 3** The major activities of the practice of health education, derived from Bartholomew et al 2006<sup>42</sup>

## 1.3 This thesis

The following paragraphs outline the overarching thesis aims, the focus of the thesis and the applied step-wise method used during the development and evaluation.

### 1.3.1 Aim

The project presented in this thesis is primarily set up with the aim to design and test a web-based communication tool. The tool aims to support (out-) patients with their conversational contributions during their consultations in oncology care. The secondary aim was to examine the feasibility of granting patients more control in the execution of a research project by involving them in the development of this tool and its corresponding evaluation and implementation plan. The objectives that resulted in the separate in-depth studies being part of this thesis are introduced in the last part of this chapter. Some of these objectives were derived from the overarching aim. Others arose during the course of the project and were the result of intermediate findings.

### 1.3.2 Target group

The studies presented in the chapters mainly focus on patients diagnosed with malignant lymphoma (box 1). Given the variety in age of onset, clinical courses and treatment options, lymphoma patients form an extremely heterogeneous group. They are sometimes confronted with treatment regimens with curative intent; sometimes with only palliative therapies, but with a perspective of long term survival. The study presented in chapter five focusses on professionals in oncology care (physicians and nurses).

### Box 1 Malignant lymphoma

Malignant lymphoma is a malignancy demonstrated by an abnormal growth of cells in the lymphatic system. The disease can start almost anywhere, as lymphoid tissue is part of the immune system and present in many parts of the body (figure 4). Lymphomas are unique in that they cover a wide range of conditions. Two major groups can be distinguished, i.e. Hodgkin Lymphoma (HL, about 10%) and Non Hodgkin Lymphoma (NHL, about 90%). HL is named after Thomas Hodgkin, who described the disease in 1832. HL can occur in both adults and children but the age of onset is most common in early adulthood. Classical Hodgkin lymphoma is the most common variant and is characterized by painless lymphadenopathy and general symptoms as loss of weight, fever and night sweating. Per year, in the Netherlands approximately 450 patients are diagnosed with HL (2014)<sup>46</sup>, and 5600 in Europe (2010)<sup>47</sup>. NHL is the overarching term for the more than 50 variants of lymphomas. NHLs are a group of conditions that can occur at any age, but about half of the patients are older than 66. Over 4200 patients are each year diagnosed with NHL in the Netherlands (2014)<sup>46</sup>, and 58000 in Europe (2010)<sup>47</sup>.

The course of all these variants lymphomas varies widely, from very aggressive histology's to the most slow-growing malignancies. Accordingly, a range of treatment options are applied, including chemotherapy, radiotherapy, immunotherapy and stem cell transplantation. In some forms of indolent NHL causing little or no symptoms, watchful waiting (or wait-and-see) is the best strategy. For the past decades, advances in lymphoma treatment have led to strongly improved survival. Nevertheless, survivors have to deal with short-term, long-term and late treatment effects. Lymphoma patients often face multiple challenges during the period from first complaints until diagnosis and treatment with many important decisions to be taken. After this primary phase of diagnosis and treatment, most patients face long monitoring periods, a high incidence of second primary cancers at remission<sup>14</sup>.

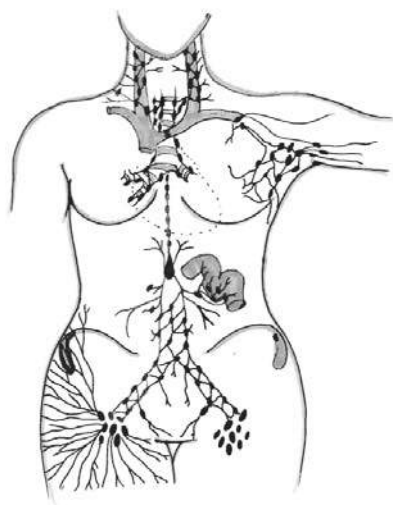


Figure 4 The lymphoid system



### 1.3.3 Internet based technologies for health care

Internet Based Technologies (IBT) are nowadays (2016) used on a daily basis by young and old. In 2013, 97% of the Dutch inhabitants had access to the internet and 88% of this group used the Internet on a daily basis<sup>48</sup>. Accordingly, also IBT in patient-targeted interventions are increasingly offered and used. These interventions are often referred to as e-Health, and vary from informational websites, self-management and treatment tools to digital patient records<sup>49</sup>.

The Internet can deliver tailored interventions accessible at any time and place in a cost effective ways. With regard to knowledge and skills building, the effects of web-based interventions for patients seem to be equivalent to traditional medical education methods (e.g. a printed or face-to-face delivered interventions)<sup>41-43</sup>. In this context, an increase of interventions in oncology care delivered via the Internet seems evident.

The intervention developed as part of this thesis is delivered via a web-based platform called 'PatientTIME' (Patients Talk In Medical Encounters, box 2). The study was set up in 2010 and started in 2011 with the development phase. The evaluation of the intervention PatientTIME took place from 2013 to 2015.

#### Box 2 The PatientTIME intervention

The web-based PatientTIME intervention aims to support patients in gaining more control over the communication with their health care professional. Patients can use this intervention prior to their hospital visit to prepare their clinical consultation. Use of PatientTIME is patient-initiated and fully automated. The intervention is developed in close collaboration with patients and makes use of different theory-based methods; modelling, tailoring information, pre-visit goal setting and listening back, delivered via personal accounts. The central information of the intervention consists of short video fragments (47-180 sec) showing simulated patients modelling different communication skills during medical encounters (e.g.; utter the need for support; deal with emotions; ask questions). The fragments are based on communication barriers identified by the targeted population (chapter two). Additionally, a question prompt sheet, and an option to replay an audio-recording of the hospital visit were integrated.

### **1.3.4 Applied Methods**

A mix of methods was used to develop and test the PatientTIME intervention in a patient-centred way. The approach applied included both qualitative and quantitative research methods.

#### **A patient participatory, step-wise approach**

The Intervention Mapping (IM) framework was used as theoretical backbone to develop the intervention with a corresponding evaluation and implementation plan. The IM framework is a step-wise protocol used to guide the planning and decision-making process in health education programs<sup>42</sup> (figure 3), aiming at the development of evidence-based interventions. To involve (seriously ill) patients in the development, evaluation and implementation of the intervention, patient participatory methods were integrated in the IM framework. Patients were involved on different levels, including initiation of the research question, involvement in the organization, goal setting, planning and execution of the project.

#### **A randomized Controlled Trial**

The evaluation of PatientTIME was partly stipulated in the research protocol, which defined a randomized controlled trial (RCT). The development of the evaluation plan was influenced by patient representatives. The RCT was registered in the Dutch Trial Register ([www.trialregister.nl](http://www.trialregister.nl) id number: 3779). Participants were asked to participate in the RCT for a maximum of three consultations. They were asked to complete online questionnaires via their secured PatientTIME account to evaluate their communicative experiences.

To assess the effectiveness of PatientTIME, the primary outcome measure inquired patient's confidence in the ability to communicate with their health care professional. On a second level, patients were encouraged to verbalize their ideas and experiences with the use of the web-based intervention. For the purpose of evaluating the 'listen back' option, a pilot was designed as part of the RCT. To this purpose, a random subset of patients were encouraged to audio-record and upload their consultation(s) in their PatientTIME account.

#### **Implementation**

The implementation of PatientTIME to a publicly available tool was prepared parallel to the development and evaluation of the intervention. Contrary to the detailed development and evaluation plan, the implementation plan was a rough setup of actions that were guided by and adapted to decisions related to the development and evaluation. To increase the chance of a successful implementation and

adoption, the involvement of patients and patient association Hematon (the Dutch patient association for leukemia, malignant lymphoma and stem cell transplantation, former LVN), started as early as the project planning. The (evaluation of) the actual transfer of the intervention is not part of this thesis.

### 1.3.5 Collaboration

A multidisciplinary working group consisting of researchers, health care professionals and patients was responsible for the project (figure 5). The daily coordination and execution was based at NIVEL, (Netherlands institute for health services research). Health care professionals from the Radboud University Medical Centre and the VU University Medical Centre were regularly involved to advise on the intermediate steps. A close collaboration with the patient organization Hematon was established to incorporate patients' advice and perspective from the start of the project. The project was funded by the Alpe d'HuZes program of the Dutch Cancer Society.



Figure 5 Partners

## 1.4. Thesis outline

As part of the applied step-wise protocol we conducted a series of studies in cooperation with patients and health care providers (figure 6). Chapter 2 to 7 of this thesis describe six studies in further detail;

*What helps and hinders patients diagnosed with malignant lymphoma in their communication during medical consultations?*

**Chapter 2** presents the results of the needs assessment conducted among patients diagnosed with malignant lymphoma. This first step in the development protocol aimed to get insight into barriers and facilitators patients perceive when communicating with their health care professionals. In this study we applied a qualitative method, derived from the context-mapping framework. The findings of this study were used as a basis for the content development of the communication support.

*How can we involve (seriously ill) patients in the development, evaluation and implementation phase of a patient targeted communication intervention?*

**Chapter 3** presents the applied participatory protocol used to let patients guide the content development of the web-based communication tool ‘PatientTIME’ with corresponding evaluation and implementation plan. This chapter focusses on the participation of patients on different levels throughout the entire project. We conclude with our lessons learned in the attempt to ensure patient participation.

*Is the context of the video fragments not too overwhelming and are the modelled communication strategies remembered as intended?*

**Chapter 4** presents the experiment that was conducted to evaluate the central content of the intervention (video fragments) in further detail. The aim of the experiment was to investigate the influence of watching three video clips on analogue patients’ emotional arousal and information recall. In 75 analogue patients the real-time emotional arousal was measured with physiological responses (electrodermal activity and heart rate). Afterwards the self-reported arousal and recall of information was inquired with a questionnaire.

*What are the experiences and views of health care professionals in oncology care regarding consultation audio-recordings?*

**Chapter 5** presents the results of a survey about consultation audio-recordings among 215 Dutch health care professionals working in oncology care. In the PatientTIME evaluation, a pilot study was incorporated stimulating patients to record their consultation. The aim of the survey was to provide insight in the experiences and views on the other side of the table; the professionals.

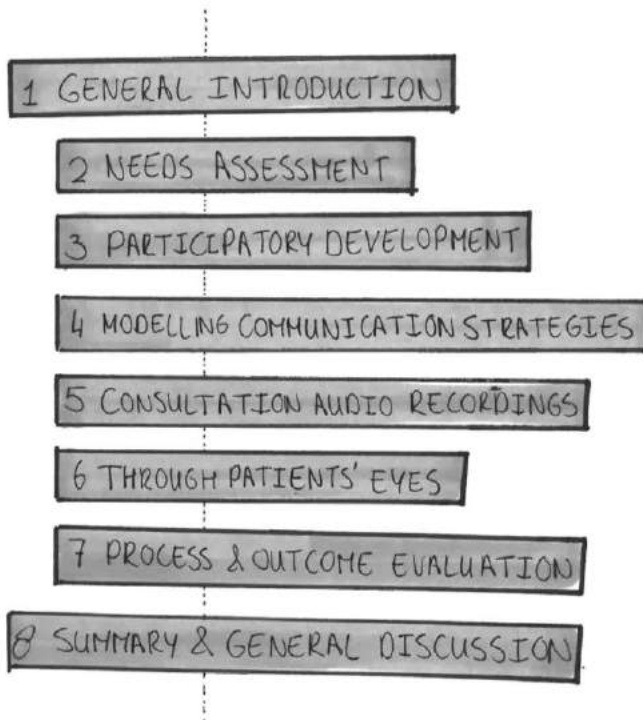
*What are the patients’ preferences and perceived performance regarding the communication during hematological consultations?*

**Chapter 6** presents a study that aimed to get insight in patients’ preferences and perceived performance regarding the communicative behavior of their health care professional. Secondary, the influence of PatientTIME on these perceptions was analyzed. Data collected via questionnaires in a controlled pre- and post-test study was analyzed. In total 78 clinical consultations of 78 patients with a hematologic malignancy were included.

*(How) do patients benefit from the PatientTIME intervention?*

**Chapter 7** presents an integrated process and outcome evaluation of the developed PatientTIME intervention. The intervention was evaluated in a closed randomized controlled trial with continuous recruitment and data collection. The aim of this study was to evaluate if and in what way patients benefit from PatientTIME and more specifically, if the intervention increases participants' confidence in interaction with their health care professional.

To conclude, **Chapter 8** presents the summary and general discussion. We reflect on the chosen research methods and results of conducted studies and further implications for policy, research, patients (or patient organizations) and clinicians are being discussed.



**Figure 6** Thesis outline

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# 2

## Barriers and facilitators to effective communication experienced by patients with malignant lymphoma at all stages after diagnosis

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*Published as:*

van Bruinessen IR, van Weel-Baumgarten EM, Gouw H, Zijlstra JM, Albada A, van Dulmen S. Barriers and facilitators to effective communication experienced by patients with malignant lymphoma at all stages after diagnosis. *Psychooncology*, 2013 Dec;22(12):2807-14.

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## Abstract

**Objective:** This study aims to gain insight into patient-perceived communication barriers and facilitators at different stages after the diagnosis of malignant lymphoma. We have detected patterns to explain when these factors influence communication predominantly.

**Method:** A qualitative approach was applied, derived from the context mapping framework. A total of 28 patients completed a set of assignments about their experiences with provider-patient communication during medical consultations. Subsequently, these patients and nine companions shared their experiences during a semistructured (group) interview, which was recorded on audiotape. The audiotapes and assignments were analysed with MAXQDA software.

**Results:** From the patients' viewpoint, communicating effectively appears to depend on their own attributes (e.g. emotions), the health care professionals' attributes (e.g. attitude) and external factors (e.g. time pressure). Three patient communication states were identified: (i) overwhelmed, passive; (ii) pro-active, self-motivated; and (iii) proficient, empowered. Patients seem to behave differently in the three communication states.

**Conclusions:** This study lists patient-perceived communication barriers and facilitators and identifies three different communication states, which indicate when certain barriers and facilitators are encountered.

**Practical implications:** These findings may support health care professionals to tailor the provision of support and information and remove communication barriers accordingly. Additionally, they provide input for interventions to support patients in effective communication.

## 2.1 Introduction

Effective patient-provider communication is essential for optimal cancer care [1] and helps patients to cope with the disease in everyday life. In effective communication, both parties are actively involved in achieving satisfaction as well as better health and psychosocial outcomes [2–5]. The PACE curriculum, designed to teach patients how to communicate effectively and integrated in patient communication interventions [6–9], lists four components necessary for effective patient communication: (i) Presenting detailed information; (ii) Asking questions; (iii) Checking and understanding; and (iv) Expressing concerns. Bylund et al. suggest adding (v) State preferences to this list [10]. These components require a maximum effort of patients.

The often suboptimal quality of communication in cancer care [11] improves when health care professionals (HCPs) tailor information to individual patient needs [12–14]. To provide tailored information, HCPs need to attend to patients' changing needs and adapt the communication accordingly. Patients can contribute to this process by clearly expressing their needs and preferences [15]. Many patients prefer such an active role during consultations [16]. Even at a governmental level, the importance of a participatory role of the patient is underlined [17,18]. However, the actual contribution of cancer patients in clinical practice is often limited [19–21], suggesting a discrepancy between the patients' preferred and actual role [16,22] and patients continue to have unmet communication needs [11]. Apparently, patients are hindered by barriers to participate actively.

Recent research reveals the potential benefit of training patients to overcome communication barriers [4,5,23,24]. However, to our knowledge, only a few studies address the nature of communication barriers from a patient's perspective [25–28]. Such knowledge would help to tailor training interventions to patients' needs. In accordance with the communication framework of Feldman-Stewart [29], communication barriers relate to attributes (emotions, skills, values, beliefs and needs) of both patient and HCP and external factors. A recent study of oesophageal cancer patients reveals that patients' perceived communication barriers mostly reflect dysfunctional beliefs (e.g. expecting negative consequences of raising a subject) and skills (remembering questions only afterwards) [25]. These findings also show that barriers might be specific for the type of cancer because of disease-specific issues that patients have to deal with (treatment complications, physiologic alteration and psychosocial problems).

Because of this disease-specificity, the current study focuses on patients with

malignant lymphoma, currently the seventh most common cancer diagnosed in Europe [30] with two distinguished groups: Hodgkin's lymphoma (HL) and non-Hodgkin's lymphoma (NHL). Long treatment and control periods for Hodgkin's lymphoma and non-Hodgkin's lymphoma (N)HL patients might result in additional, disease-specific barriers and facilitators. After treatment, the majority of lymphoma patients face a very long period of intense monitoring under specialist care because of the chance of recurrence, the high incidence of second primary cancers, complications of treatment [31] and because many NHL patients never achieve a complete remission. Also, some patients will not receive treatment immediately after diagnosis and are confronted with regular medical check-ups (wait-and-see policy). Given this long period of monitoring and the knowledge that patients' preferences change over time [21,22,32], it is likely that patients' communication preferences change accordingly.

As most studies focus on the diagnosis and treatment phase [33], we aim to identify communication barriers and facilitators at all stages after diagnosis. More specifically, we aim to gain insight into patients' ideas about what supports and hinders them to achieve effective communication, and to identify patterns within the perceived barriers and facilitators.

## **2.2 Method**

A qualitative approach was chosen to learn from the experiential knowledge of the patients. We wanted to know how patients reach their goals in communication or why they do not. Following the Dutch Medical Research Involving Human Subjects Act, this study does not require ethics approval.

### **2.2.1 Participants**

Patients (>18 years old) diagnosed with malignant lymphoma were included. Those who would usually bring a companion to the consultations were encouraged to invite this person to their interview. In general, many patients do bring a companion [34,35], and they can play an important role in communication [34,36–38].

### **2.2.2 Recruitment**

In March 2011, the study was introduced at the annual congress and two regional meetings of the Dutch patient association for Lymphoma cancer (LVN) where patients could sign up. Additionally, a nurse in haematology introduced the study to her patients. Interested patients received a letter with information and a

questionnaire about their diagnosis. If patients were unable to attend a focus group discussion, for example because of travel distance or health, they were interviewed at home.

### **2.2.3 Study design**

We have followed a two-step approach derived from the context mapping framework [39].

#### **Step 1: sensitizing**

One week prior to the (group) interview, participants received a booklet (probe) with questions. The primary aim of these probes was to trigger patients to verbalize experiences, preferences and needs, and to reflect on it. This so-called sensitizing process is supposed to enhance the quality and quantity of the patients' contributions in later (group) interviews [40]. Secondary aim of the probes was to study the patients in their own context, without the presence of researchers or other patients. The leading questions of the probe were checked by a patient expert (HG). To encourage patients to think more freely, we included a set of words and graphics illustrating common feelings.

#### **Step 2: (group) interviews**

Participants were asked for permission to audiotape the interview. A semistructured set-up was used to avoid the influence of preconceived notions and to allow patients to express themselves in their own terms [41]. The facilitator (IB or AA) asked leading questions about experiences, needs and preferences in relation to the time they emerged (before, during or after a consultation), the stage of the disease (diagnosis, treatment or follow-up) and the HCP involved (specialist, nurse or general practitioner). Questions subsequently focused on how the patient behaved in the consultation and how he/she would like to have acted. During the interviews, the facilitator explored topics in further detail while during the group discussions participants were particularly encouraged to react to each other's experiences and to indicate whether they shared experiences.

### **2.2.4 Data analysis**

The data of this study consists of the verbatim transcriptions of all audiotapes and comments from the booklets. The coding, sorting, clustering and comparison of fragments was facilitated by MAXQDA software [42]. Fragments about factors that

influence the communication were coded as well as perceptions, values, needs and wishes. 'Open coding' (initial codes given to fragments of text) was gradually replaced by 'axial coding' (describing codes and integration in broader related concepts) to find patterns. Due to the overlap with the communication framework of Feldman-Stewart [29], the coding scheme was organized according to the main domains of this framework.

After having double coded several transcripts and having compared reliability (IB/EW/AA), IB coded all transcripts and discussed new codes and unclear fragments with the other authors. To further improve the quality of the analyses, EW and AA double coded a transcript again at different points. This 'peer debriefing' [43] prevents one-sided interpretations of the data. We have coded four topics for each selected fragment: (i) the factor that influenced the communication; (ii) whether this factor was experienced as a facilitator, barrier or neutral; (iii) when the situation took place; and (iv) the HCP involved (Figure 1). Finally, IB and AA double coded a transcript to determine the interrater reliability. There was agreement on 95% of the text fragments to be coded. Within these text fragments, the coders agreed in 74% on the factor that influenced the communication, in 76% on whether this factor was experienced as a facilitator, barrier or neutral, in 91% on the time phase and in 88% on who was involved. Since the last interviews provided no new themes related to the research questions, data saturation appears to have been reached.

## **2.3 Results**

### **2.3.1 Respondent and interview characteristics**

In total, 32 patients have been registered. All fulfilled the inclusion criteria. Four patients resigned before the start of the data collection because of a worsening physical condition. The 28 participating patients were on average 59 years old (Table 1). Nine patients brought a companion (all spouses). At the time of the interview, 10 patients were in active treatment, four were facing a wait-and-see policy and 14 were in remission. Prior to their current status, three patients had experienced one or more periods of wait-and-see and 23 had undergone one or more periods of treatment.

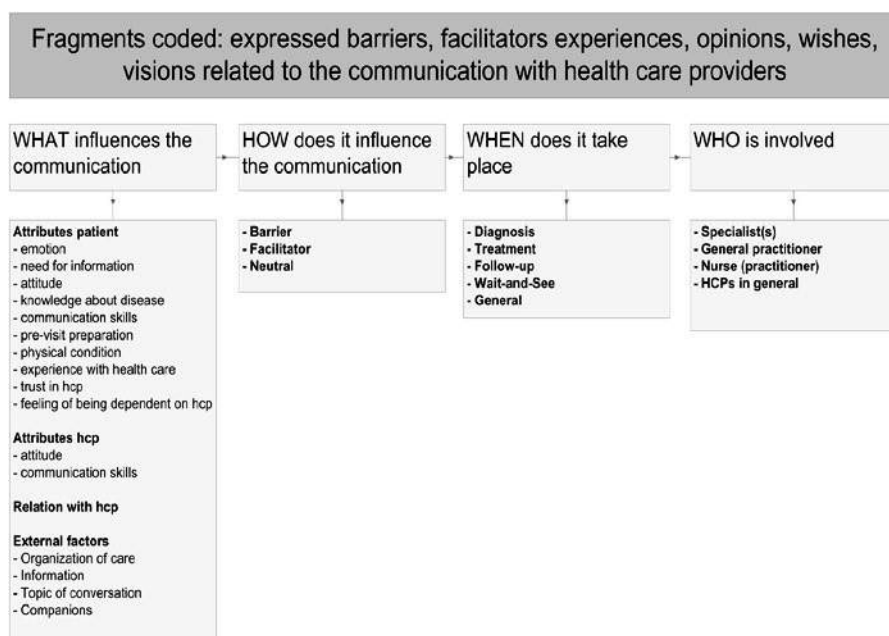


**Table 1** Characteristics participants

	Patients (n = 28)	Spouses (n = 9)
Men	12	4
Women	16	5
Average age(range)	59(39–81)	
Average time since diagnosis(range)	7 years (3 months–29 year)	
Diagnosis	5 Hodgkin 23 Non-Hodgkin	
LVN member	25	

### Probes

The probes were completed by 21 patients before the interview, two patients completed the probes afterwards. Five patients did not return the assignments (three men/two women; 4 NH/1 H; mean age 62 (39–73)). Two of them indicated as a reason that they lacked the time, three of them had not received the booklet in time.



**Figure 1** Fragments coded: expressed barriers, facilitators experiences, opinions, wishes and visions related to the communication with health care providers

### Focus group discussions and interviews

Three focus group discussions were conducted with four to nine participants and 10 interviews of which one included two patients. Group discussions and interviews lasted approximately 103 (85–128 min) and 55 min (30–95 min), respectively. Spouses attended four of the 10 interviews and two of the three focus group discussions.

### 2.3.2 Communication barriers, facilitators and ambiguity

In this section, the expressed barriers, facilitators and ambiguity (when a factor is experienced as a barrier for one patient, but as a facilitator for another) are described and illustrated with quotes. Subsequently, a pattern in the different communication states is described.

#### Barriers related to the patients' attributes

Frequently mentioned barriers in the domain of patient attributes were emotions experienced before (stress and uncertainty) and during (anxiety, sadness and desperation) the consultations.

*'Then your thoughts start rambling and you don't hear what else the doctor has to say'.*

Patients also mentioned their lack of specific knowledge about their disease, lack of communication skills and experience with the consultations.

*'I have the feeling, that man is talking, but I don't understand any of it'.*

These barriers were expressed in forgetting to ask (prepared) questions, having difficulties in processing discussed information and not knowing how to ask for clarification.

*'Often when you have asked a question, you get an answer and you have to think it over. And then the consultation is finished before you have thought about it. Then you start to think, oh what are they sending me home with this time'.*

Hindering beliefs that patients mentioned were the feeling of being dependent on the physician and the idea that a physician did not appreciate an actively participating patient.

*'I often get the impression that it is not appreciated if you ask too many questions'.*

Other hindering beliefs were that (vague) complaints were not worth mentioning

and the conviction that patients should not interfere.

*'You do not want to be a nuisance. You understand that she is very busy. You see the entire waiting room full of people'.*

### **Barriers related to the health care professionals' attributes**

The majority of the coded fragments related to situations involving hospital physicians. Specific communication behaviours of physicians were frequently mentioned as a barrier, for example keeping the conversation too general, not responding to patient's notice of vague physical or psychological complaints, not apologizing for mistakes and a blunt delivery of bad news. Additionally, a professional's haughty or hasty attitude, the perceived poor cooperation with other HCPs or departments and an overly technical and non-psychosocial communication style, hindered patients in their communication (*values, believes and emotions*).

*'I have to be quick with my questions, because I always feel that the doctor is in a rush to get finished with the consultation'.*

Few fragments related to GPs, nurses or nurse practitioners. Most interviewed patients rarely consulted the GP after the diagnosis (N)HL was made and the possible role a GP can play was unclear to them.

### **Barriers related to external factors**

A frequently mentioned organizational barrier was time pressure, that is waiting before a consultation (evoked, e. stress, anxiety and related *emotions*), the amount of time during a consultation (*skills*) and the length of time until results of medical tests were communicated (evoked frustrations, anxiety and related *emotions*).

*'I also think that doctors are not aware of how much of a burden waiting is. You can't go anywhere with your feelings. Then you enter the consulting room already very stressed'.*

Other barriers are discussed in the paragraph 'ambiguity' as they were also experienced as facilitating factors, depending on the setting.

### **Facilitators**

Many opposites of the barriers were mentioned as facilitators. An additional aspect concerned the patient's belief that one has a responsibility to look after oneself and, therefore, one needs to know what is going on.

*'In this whole process I want to stay in control and nobody else. This is my life'.*

Also, preparing questions and entering the consultations with specific goals in mind

supported patients to ask questions and engage in discussions.

*'You must come prepared. You have write down everything that crosses your mind in a notebook or on a list'.*

The need to keep control (i.e. managing medical records, planning consultations at a preferred time and asking for a one-to-one conversation) was another facilitator as was a good relationship with the HCP.

*'The moment you want to build a relationship with a doctor, and you have certain questions, you have to bring them up yourself, you have to be open-minded... You have to work together on the relationship'.*

Patients also mentioned that it helped when a physician showed a reflective communication style and addressed the communication rules between them, that is the meta-communication.

*'The best thing is when someone explains it very thoroughly. And then also checks if you have understood it'*

*'Then she asked – without speaking about medical matters –: We are committing to a long term control period, how do you want us to communicate with each other? That completely opened up everything'.*

## **Ambiguity**

Several factors, mainly in the external domain, were experienced as both barriers and facilitators. For example, the information patients gathered on the Internet motivated some patients to ask questions and start discussions while it made others feel confused or more stressed. Also, the opinions on the continuity of care varied. Some patients were more at ease seeing the same physician at every hospital visit. Having a familiar physician supported them in asking questions or discussing concerns. Others felt more confident sharing their concerns with several haematologists who cooperated in determining the treatment policy. Most patients had companions to help them raising concerns.

*'My wife always brings a paper with her, so we can write down things if necessary and in case I forget something, she will ask it'. 'Because you are together, you can have a different sort of conversation. You can complement each other'.*

Others mentioned that bringing a companion distracted them or made them feel uncomfortable.

*'You also have things you only dare to ask or say if you are alone with the doctor. If your family is there, you can feel a bit embarrassed'.*

### 2.3.3 Three communication states

The data showed that patients' communication attitudes and skills changed over time and so did the perceived barriers and facilitators. A pattern was observed in when certain barriers and facilitators were experienced, and this pattern could be described as three progressive communication states: (i) overwhelmed, passive; (ii) pro-active, self-motivated; and (iii) proficient, empowered.

Patients who were easily overwhelmed and who contributed little to the conversation characterized the first state. Emotions (fear, uncertainty and sadness), lack of knowledge about the disease (not knowing what to ask) and lack of knowledge about the health care system (not knowing what to expect when and from whom) were important barriers.

*'In the beginning you don't even know what you want to know'. 'You get blocked and you think: tomorrow I'll die. You do not hear anymore what the specialist is telling you'.*

In this first state, patients also mentioned their distrust of health care as a result of the long period of uncertainty until the diagnosis of (N)HL and the feeling of being dependent as communication barriers. A patient seemed to go to the second communication state if the need to understand what was happening resulted in asking questions and learning about the disease.

*'I realized that it was very important to pay attention: be aware of what's happening, remain calm and focussed, so I know what is going on, what is going to happen and why'.*

Patients who wanted to understand their situation represented this second state. They started to gather information during and between consultations. These patients tried to go to consultations better prepared and with certain goals in mind. Examples of barriers experienced in this state were lack of communication skills, feeling dependent on the physician (not daring to utter disagreement or ambiguities), conflicting information sources and limited time of the consultation.

*'I always tried to be as clear as possible. But sometimes I wasn't to the point. I did not know exactly what I wanted'.*

During this state of learning, the patient became more skilled and experienced and gradually shifted to the third state. In this third state, patients experienced fewer barriers in communication, had an improved ability to deal with remaining barriers (predominantly external factors), experienced less difficulties reaching their communication goals and asked less, but more specific, questions.

*'My role is to indicate what my questions are and to make sure, that the other really understands my motivations. My experience is that if I indicate what I think is important for me, that they go along in that'.*

The communication states were found to be consecutive, but also fluid, as time since diagnosis or phase of the disease did not predict a certain communication state per se. Some patients started in the second state right away. However, most patients seemed to go from the first to the second state shortly after having been diagnosed. They described this as a process in which they learned that their needs were better fulfilled if they had a more active role in the consultation. For most patients, their state was not a fixed permanent entity as few never seemed to have changed between states. However, some patients never seemed to have moved from the first state because of personal attributes, negative experiences, the inability to understand what is happening or the persisting attitude that there was nothing to say.

## 2.4 Discussion

### 2.4.1 Barriers and facilitators to effective communication

Most facilitating factors to effective communication experienced by patients with malignant lymphoma seem to concern the patient's need for control over the situation and the emerging need for information. These needs urge the patient to participate actively by asking questions, asking for clarification, addressing new topics and voicing concerns/disagreements and stating preferences. That is components needed for effective communication according to the PACE curriculum and Bylund et al. [10].

Several attributes of HCPs were experienced as facilitator or barrier. An example of a barrier is when physicians keep the conversation too general. This finding concerns physicians' underestimation of patients' desire for information [44]. The ambiguity found in how factors affected communication, such as the enhancing or inhibiting effect of the presence of a companion, indicates the need for tailored support and advice.

Many communication barriers and facilitators did not seem to relate to disease-specific issues, such as the disruptive role of emotions and the facilitating role of previsit preparation, and may therefore be relevant to other cancer patients too. For example, the predominant barriers experienced by oesophageal cancer patients were their dysfunctional beliefs and lack of skills [25], and these were also

considered as important barriers by the participants in the current study. However, the importance or prevalence of specific barriers and facilitators may differ across cancer types. For example, the distrust towards HCPs of patients with malignant lymphoma as a result of the long period of uncertainty until the diagnosis might be specific for NHL patients as the disease often starts with vague physical complaints.

#### **2.4.2 Three communication states**

Barriers and facilitators in communication with the health care practitioners seemed to differ along three states: (i) overwhelmed, passive; (ii) pro-active, self-motivated; and (iii) proficient, empowered. These three communication states conform to the 'conscious competence learning model', referred to by Maslow, who describes the stages of learning a new skill from unconscious incompetence to unconscious competence. Most patients in the first communication state are unconsciously incompetent as they are unaware of the role they can play. Elements of the first state have been described by Borgers et al. [28] stating that one quarter of the cancer patients are not aware of their own intention. Also, Robinson and Thomson [45] argue that patients may be unaware of the benefits they can gain by active participation in the consultation. The participants in this study frequently discussed this concept of awareness and it might clarify the transition from the first to the second state. When a patient realizes the importance of understanding what happens, it triggers a change in attitude. Moreover, hindering values and beliefs were found to explain the differences in communication behaviour identified in the first and second state (I am afraid to distract my physician from curing the cancer if I start talking about psychosocial problems). When patients become aware of the role they can play and the skills they need, they start to learn. In this state, conscious competence (e.g. asking prepared questions) alternates with conscious incompetence (e.g. not able to ask for clarification when the answer is not clear). In the third communication state, the patients are unconsciously competent and they have knowledge and skills to fulfil their needs. The transition to this third state appears to evolve more gradually and involves the patient experiencing more control. The increasing emphasis on patient autonomy and participation [45] and the positive outcomes related to participation [2,46] suggest that it might be worthwhile to support patients with skills facilitating the transition to the third communication state.

### **2.4.3 Strengths and limitations**

We have tried to include a broad range of patients with malignant lymphoma by announcing the study in several different ways. Although the participants represent various regions, various stages of the disease and they attended different hospitals, 78% of the group are member of the LVN. Additionally, patients themselves could take the initiative to sign up for this study. We presume that the participants were more assertive and experienced than the average patient.

However, their experiences helped them to reflect on consultations where they felt less empowered, which was essential to identify communication barriers at different phases. The context mapping method might also have facilitated participants' ability to reflect on the barriers and facilitators experienced in their communication in consultations. During the following (group) interviews, the participants seemed well prepared. The sensitizing process, thus, seems to have enhanced the participants' contribution as intended. In general, the participants were positive about the applied method, and the probes enriched the data gathered in the interviews. The context mapping method seems appropriate for this type of research. Despite the non-directive formulation of questions, most quotes describe communication with physicians in hospitals. Overall, the results of interviews and group discussions did not differ much. Participating spouses mainly underlined patients' expressions and contributed to the interview when the role of a companion was discussed. Due to the retrospective character of the study, recall bias might have affected the results.

### **2.4.4 Conclusions**

This study revealed communication barriers, and facilitators experienced by malignant lymphoma patients in their communication with HCPs. A pattern was observed and described as three communication states that indicate when certain barriers and facilitators are encountered.

### **2.4.5 Practical implications**

Health care professionals should become aware of the changing, or sometimes persisting aspects that facilitate or hinder the way patients contribute to the consultations. The categorization of three communication states might help HCPs to tailor information and to remove communication barriers. The HCP can also play a role in creating awareness about the patients' role in a consultation. Even though most training programs focus on communication skills for the HCPs, patients may benefit from communication training as well [7,47]. Results of this study can be used



to design training programs for both HCPs and patients.

### **Acknowledgements**

We are grateful to all participants for sharing their experiences; LVN and Corien Eeltink for their advice and help with recruitment; the Alpe d'HuZes programme of the Dutch Cancer Society for their financial support; Bianca Wiering and Melissa Gultzow for transcribing the audio tapes; Jayne Jubb for her help with translating the quotes and Lydia Kapsenberg for her advice on a previous version of this paper.

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# 3

## Active patient participation in the development of an online intervention

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*Published as:*

van Bruinessen IR, van Weel-Baumgarten EM, Snippe HW, Gouw H, Zijlstra JM, van Dulmen S. Active patient participation in the development of an online intervention. *Journal of Medical Internet Research Protocols*, 2014 Nov 6;3(4)e59.

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## Abstract

**Background:** An important and challenging part of living with cancer relates to the repeated visits to the hospital. Since how patients cope between these post-diagnostic visits depends partly on the information and support received from their physician during the visits, it is important to make the most of them. Recent findings reinforce the importance of training not only the health care professionals in communication skills, but providing patients with support in communication as well. Delivering such supportive interventions online can have potential benefits in terms of accessibility, cost-effectiveness, and ability to tailor information to personal needs. However, problems with attrition (dropout, non-usage) during the test phase and poor uptake after implementation are frequently reported. The marginal level of engagement of the patient as end user seems to play a role in this. Therefore, recent research suggests integrating theory-based development methods with methods that promote involvement of the patient at an early stage. This paper describes a participatory protocol, used to let patients guide a theory-informed development process.

**Objective:** The objective of this project was to apply a bottom-up inspired procedure to develop a patient-centered intervention with corresponding evaluation and implementation plan.

**Methods:** The applied development protocol was based on the intervention mapping framework, combined with patient participatory methods that were inspired by the participation ladder and user-centred design methods.

**Results:** The applied protocol led to a self-directed online communication intervention aimed at helping patients gain control during their communications with health care professionals. It also led to an evaluation plan and an implementation plan. The protocol enabled the continuous involvement of patient research partners and the partial involvement of patient service users, which led to valuable insights and improvements.

### Conclusions

The applied protocol realized patient participation on different levels throughout the entire project. Early involvement, involvement on different levels, and flexibility in terms of planning and setup seem to be preconditions to creating a bottom-up inspired development procedure with (seriously ill) patients. Further research is necessary to find out if a more patient-centered approach improves the implementation and uptake of eHealth interventions.



### 3.1 Introduction

An important and challenging part of living with cancer concerns the repeated visits to the hospital. These visits are important as they monitor the development of the disease and set the stage for how to cope with life until the next consultation. Since how patients cope between these post-diagnostic visits depends partly on the information and support received from the health care professionals (HCPs) (eg, specialists, nurses) during the visits, it is important to get the most out of them. Many training programs are designed to improve HCPs' communication skills, which may facilitate patient engagement in the medical dialogue. However, cancer patients ascribe many barriers in medical communication to their own attributes, such as a lack of communication skills, and interfering emotions and beliefs [1,2]. These findings reinforce the importance of training not only HCPs in communication skills, but providing patients with support in communication as well. Epstein and Street (2007) have stressed the need for developing specific types of interventions to support cancer patients, such as in-person coaching, interactive computer programs, videos of role models, and question prompt sheets [3].

Such interventions can be especially efficient when delivered online. The content and type of online interventions can be computer tailored to patients' preferences and needs and they can be accessible any time and any place in a cost-effective way [4]. With regard to knowledge and skill building, the effects of online interventions for patients seem to be equivalent to traditional medical education methods (eg, a brochure or human-delivered intervention) [5,6]. Despite these potential benefits, problems with attrition (dropout, non-usage) during the test phase and poor uptake after implementation are frequently reported [7-9]. According to Eysenbach, characteristics related to the participants, the intervention, and the study design influence the usage and adoption success of online interventions [10].

The technology- and expert-driven development methods (top-down) are indicated as possible causes for attrition and adoption problems [11]. These imply a marginal level of engagement of the involved end-users (especially patients). Therefore, recent research suggests integrating methods that promote involvement of the patient at an early stage (bottom-up) with theory-based intervention development methods [11,12]. Patient participation is frequently referred to, the potential benefits are widely accepted, and there is a clear urge for more patient involvement [13]. However, the actual operationalization, that is, how and when (seriously ill) patients are involved, is rarely reported [14,15]. It often seems a more symbolic statement or it is used to describe the participation of patients in health

programs. This differs from patients' active involvement in the organization, goal setting, planning, and execution of interventions [16].

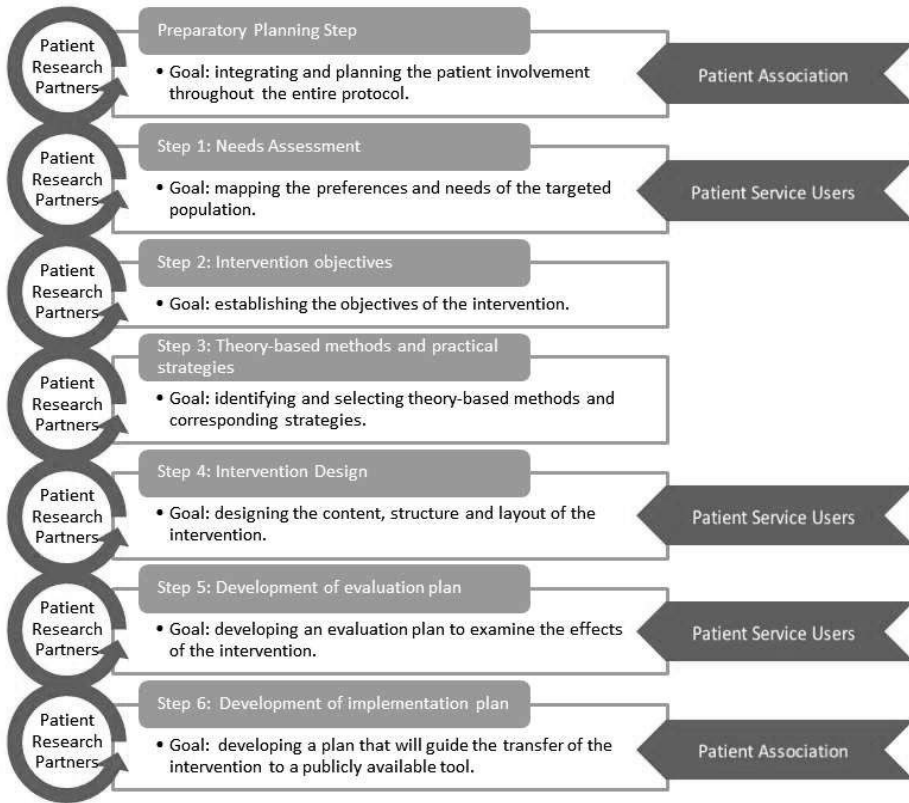
Considering the fact that the contribution of patients in oncology consultations is often limited [3,17,18] and that patients ascribe many communication barriers to personal attributes [1,2], the PatientTIME project was set up (Patients Talk In Medical Encounters). In this project, an online intervention is developed, tested, and implemented that aims to teach patients to take more control during their consultations. The project aims to realize this with a bottom-up inspired approach, which implies the involvement of seriously ill patients throughout the entire project. The initiation of the project was triggered by a specific request for support in communication with HCPs, expressed by a group of patients diagnosed with malignant lymphoma. Lymphoma patients often face long, intense treatment periods and/or monitoring periods under specialist care, which involve many hospital visits. Apparently, despite the (mainly paper-based) information available for this group, patients with malignant lymphoma experience difficulties in communicating their own agenda and needs to their HCP.

This paper outlines the patient participatory approach used to develop an online intervention with corresponding evaluation and implementation plan. The goal of this paper is to share the applied protocol, the use of the protocol in the PatientTIME project, and our lessons learned in the attempt to create a bottom-up inspired intervention.

## **3.2 Methods**

### **3.2.1 Outline**

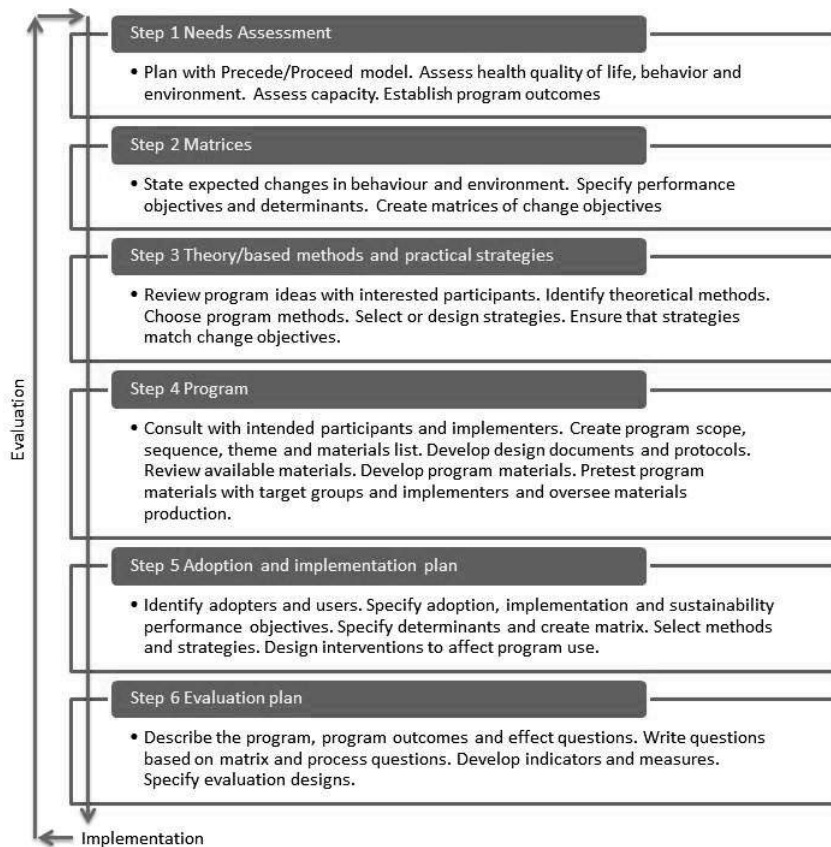
A stepwise protocol (Figure 1) was applied to develop the intervention with corresponding evaluation and implementation plan. For each step, goals were set and the procedure to involve patients was planned in advance. The Intervention Mapping (IM) framework was used as theoretical backbone of the protocol. Aiming at a patient-driven development protocol, practical patient participatory methods were integrated in the theoretical IM framework and used to inspire when and how patients could be involved.



**Figure 1** Stepwise protocol

### 3.2.2 Intervention Mapping as a Theory-Based Guideline

The IM framework systematically guides the planning and decision-making process in health promoting programs [19]. It comprises six steps in the process toward the development of a theory-driven and evidence-based intervention (Figure 2). The outcome of each step guides the next step. The IM framework has already been used successfully in developing a range of eHealth programs [20-23]. The IM framework was chosen as a guideline because it links decisions, final materials, and activities to theory. A preparatory step was added to the IM framework to plan and prepare the patient participation throughout the entire protocol.



**Figure 2** Intervention Mapping framework

### 3.2.3 Patient Participatory Methods

The way patients were involved in the applied protocol was inspired by the concept of participation ladders. Different participation ladders describe the idea of involving participants in varying degrees [24-27]. Definitions of these degrees vary, but they all describe a stepwise scheme from no participation (eg, patients participate but have no understanding of the project; they get information but there is no dialogue) to the highest possible level of participation (participants directly collaborate with the stakeholders; have an agenda-setting, initiating role). This concept inspired us to involve patients on different levels and we operationalized this by (1) setting up a close collaboration with the patient association for malignant lymphoma (Hematon),

(2) recruiting patients as research partners, and (3) planning the involvement of patient service users. Hematon informs and supports patients and champions patient interests. Patient research partners are involved throughout an entire project and they are equal partners in a working group. Patient service users are involved on different levels, in different parts of the project.

User-centered design (UCD) was used as a guide to realize patient participation in the different protocol steps. UCD is defined by Preece et al (2002) as “an approach, which views knowledge about users and their involvement in the design process as a central concern”. The challenge of UCD is to map the needs, behavior, actions, and abilities of the end user and let this information influence how the intervention takes shape. The context mapping method (Step 1) and the usability tests (Step 4) were inspired by UCD thinking.

#### **3.2.4 Patient Recruitment**

All participating patients were adults diagnosed with malignant lymphoma and they all voluntarily signed up to contribute to the project. They were recruited via social media, online newsletters, advertisements on Hematon’s website, regional and national patient conferences, and leaflets in hospital waiting rooms. To recruit patient research partners, Hematon informed several of their active volunteers (patients) who had experience in information and communication technology (ICT) development and with supporting fellow patients.

#### **3.2.5 Project Management**

A multidisciplinary working group consisting of researchers, HCPs, and a patient research partner was responsible for the daily coordination of the project. The working group collaborated with physicians, nurse practitioners, patients, user-interaction designers, software developers, and representatives of Hematon. Final decisions regarding the protocol were reached through discussions in the working group. Decisions related to the implementation plan were made in consultation with Hematon.

### **3.3 Results**

#### **3.3.1 Overview**

The intervention development protocol resulted in three products: a self-directed online communication tool, a corresponding evaluation plan, and an

implementation plan. The goal of the intervention is to help patients gain more control in the communications with their HCPs. Patients can access the intervention before each hospital visit. The information is provided via an algorithm computer-tailored to the patient's self-assessed, momentary efficacy for communication with their HCP, to whether he or she attends the HCP alone or with a companion, and to the stage of treatment. The central information consists of short video clips of simulated consultations that model adequate communication behavior. Additionally, the intervention includes an open question prompt sheet (QPS), a reminder system linked to a list of planned hospital visit dates, and an option to store and play back audio recordings of the consultation (see Multimedia Appendix 1). The evaluation plan comprises a randomized controlled trial (RCT) protocol, in which the effects of the intervention on the patients' perceived efficacy are measured in a trial setting. In the implementation plan, the conditions are built to transfer the evaluated intervention to a publicly available tool. The following paragraphs outline how the patient participatory protocol was used to develop these three products.

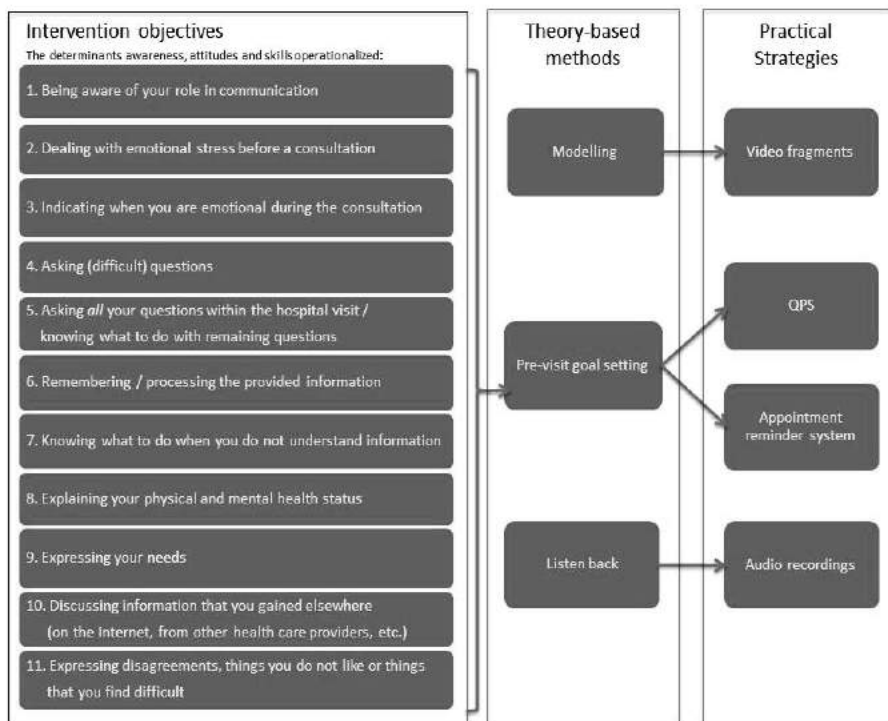
### **3.3.2 Patient Participation Planning (Preparatory Step)**

The goal of this preparatory step was to integrate and plan the patient involvement throughout the entire protocol. This resulted in the recruitment of two patients as research partners. They both had been active in supporting fellow patients and therefore they had built a rich body of knowledge about the different aspects of having malignant lymphoma. Additionally they both had a relevant professional background in ICT (Web-development, system design, research and development). One research partner (HG) became part of the working group. The second research partner was consulted on a more irregular basis. The research partners were directly involved in the planning of the PatientTIME project and in the decision-making processes in each protocol step. This involvement approach aligns with the upper steps of the participation ladder as they had an initiating and agenda-setting role and they worked directly with the other stakeholders. Additionally, patient service users were invited to participate in the needs assessment (Step 1), intervention design (Step 4), and the evaluation (Step 5). Moreover, their input was used to inspire the other protocol steps. Last, representatives of Hematon were consulted to explore the possibilities for implementing the intervention after the research project has ended (Step 6) and how we could use their network to keep in close contact with patients.

### 3.3.3 Needs Assessment (Step 1)

The goal of the needs assessment step was to map the patient-perceived barriers and facilitators in communication with HCPs and to learn from patients' experiences. A qualitative two-step method was applied, inspired by user-centered design thinking. The applied method is derived from the context mapping framework, used by product developers and user interaction researchers to gain insight into the needs of prospective users of new products [28]. Details of this study are described elsewhere [2]. In short, patients completed a set of assignments about their experiences with medical consultations, aiming to trigger them to verbalize and reflect on experiences, preferences, and needs without the presence of researchers or other patients. This so-called sensitizing process is supposed to enhance the quality and quantity of patients' contributions in later (group) interviews [29]. Subsequently, these patients and their spouses shared their experiences during semi-structured (group) interviews, which were audio-recorded. Before conducting this needs assessment, a patient research partner reflected on the study design and the formulated questions. According to his feedback, the introduction was changed to further clarify the goals of the study, more and other examples were added to illustrate the questions, and subtle changes were made to the formulation of questions (eg, avoiding medical jargon, less formal style). A total of 37 patient service users (28 patients and 9 spouses) contributed to this needs assessment. They were open, willing, and motivated to share their experiences and they all had experienced difficulties in communication during consultations. Many communication barriers were ascribed to their own attributes (eg, emotions, skills, and beliefs).

The expressed barriers were analyzed, clustered, and translated into a list of intervention objectives (Step 2) and used as a basis for the central information of the intervention (Step 4). For example, patients did not want to be bothersome and therefore they found it hard to ask (all of) their questions and to express details about their physical and/or mental health status. This information was used to develop information about how to request attention for your prepared questions (Figure 3, Objective 4) and about the importance of expressing your physical complaints and worries (Figure 3, Objective 8). Participants also reported that their communication attitude and skills changed over time, and so did their perceived barriers and facilitators. This finding stressed the need to inquire about the patient's needs before every hospital visit and tailor information accordingly.



**Figure 3** Intervention objectives, theory-based methods, and practical strategies

### 3.3.4 Intervention Objectives, Theory-Based Methods, Practical Strategies (Steps 2 and 3)

The goal of the second and third step was to establish the objectives of the intervention by specifying what would change as a result of the intervention. The overall aim of the intervention is to support patients in effective communication by creating awareness about the role they can play and the benefits they can gain from participating, as well as providing matching communication skills. Patient input gathered during the needs assessment was used to operationalize the overarching objective in 11 intervention objectives that relate to the awareness, attitude, and skills of the patient (Figure 3, column 1). These objectives were linked to theoretical methods and corresponding practical strategies. The main criterion for the selection of the strategies was the ability to operationalize strategies in an online environment that could be hosted by Hematon. Three theory-based methods and four practical strategies were selected to influence the attitude and skills of patients



(Figure 3, columns 2 and 3).

The main method chosen was modelling. Modelling has proven to be effective in patient-targeted skill building interventions [30-33] and can be operationalized in an online environment by means of video clips. Moreover, pre-visit goal setting was selected to encourage patient involvement during the consultations. This strategy was operationalized in two ways. First, the patient's appointment dates were linked to a reminder system, which reminds patients a week before their consultation to access the online intervention in order to prepare for their visit. Second, an open QPS was integrated, which could be completed and printed or sent to one's personal email address. A QPS can enhance the contribution of patients in medical communication [34-36]. Finally, there was an option to store, play back, and share audio recordings of a consultation with relatives, via their personal account. Playing back audio recordings has been shown to enhance recall, improve informed decision making, reduce anxiety, and improve communication with family members [37,38].

The intervention objectives were based on the experiences expressed by the patient service users. However, because this was a more theoretical phase comprising the literature search and the analysis of data, further patient involvement in this step was limited to a discussion with the patient research partners. The outcomes were presented and the feasibility of the operationalization was discussed, which was important for the final implementation. Their feedback did not change the initial outcomes.

### **3.3.5 Intervention Design (Step 4)**

The goal of the fourth step was to design the content, structure, and layout of the intervention, inspired by the information gathered in the previous steps. An iterative design method was applied, that is, intermediate results (eg, video scripts, website navigation) were presented to patients and experts. Subsequently, the intermediate results were adapted to their feedback, which is discussed in the following paragraphs.

The targeted intervention objectives (Step 2) were translated into five video diaries, in which five simulated patients demonstrate different communication skills. Each video diary (see Multimedia Appendix 2) displays the story of one lymphoma patient in 11 to 12 short clips (47-180 seconds). This setup was chosen to capture the experiences of a large group of patients and incorporate them in five personal stories, whereas a selection of only five patients may provide a biased view [39]. The scripts for the video clips were based on personal stories that patients had

expressed in Step 1. Additional material was gathered with video recordings and real-time observations of relevant hematologic consultations. This type of patient contribution represents the lowest step in the participation ladder as the involved patients agreed to be observed, but had no further understanding of the project. Subsequently, a patient research partner reviewed the scripts. The feedback contained suggestions and corresponding content for additional scenes and unclear medical/technical jargon was highlighted. We incorporated the additional scenes in the video clips and rephrased the highlighted sentences. After recording the clips, the rough material was shown to a physician, an ICT expert, a patient research partner, and an external communication researcher. Their feedback was used in the editing process. For example, the reactions of the doctors to patients' communication behavior were cut out as a result of the feedback, aiming to increase the focus on the modelled communication behavior of the patient.

Given the changing preferences and needs of the patient, the working group chose not to present all 58 video clips to the patient at once. The patient-perceived, pre-visit communication needs determine the selection of three most relevant objectives, leading to the matching video clips. These needs are measured with an adapted version of the 10-item, 5-point Likert scaled Perceived Efficacy in Patient-Physician Interaction instrument (PEPPI). In this scale, patients indicate pre-visit their expected efficacy and post-visit their perceived momentary efficacy in communication [40]. Based on the input of patients, two extra tailored variables were added to determine which two video diaries match the patient's situation best: (1) the patient's preference to visit their HCP alone or with a companion, and (2) the stage of treatment (ie, ahead of treatment, in the middle of treatment, in remission, cured but monitored, and wait-and-see policy). If a patient wants to prepare his or her next consultation, new clips will be selected and these will be added to their previous selection. Special attention was paid to two aspects that can influence the uptake of eHealth interventions: usability and credibility. According to Nielsen, usability is a quality attribute that assesses how easy user interfaces are to use and it is a necessary condition to bind users to a website. Credibility is an important element for the persuasive character of the intervention [41]. To enhance the persuasive character of the intervention, the Stanford Guidelines for Web Credibility were followed [42]. After testing preliminary versions of the intervention, a more comprehensive credibility and usability evaluation was performed by experts and prospective users. A heuristic evaluation (expert-based) and a think-aloud procedure (user-based) were set up with a total of 8 participants, which should be enough to

detect over 80% of the usability problems [43]. A heuristic evaluation involves having a small set of evaluators examine the interface and judge its compliance with recognized usability and credibility principles (the heuristics). The list of heuristics used to evaluate PatientTIME was composed with the 10 usability criteria of Nielsen, supplemented with usability criteria specifically developed for older Web users [44], who are expected to be over-represented in the targeted population. The Stanford Guidelines for Web Credibility were added to this list, in order to objectively evaluate the aforementioned Web credibility. The list included themes such as consistency, user control, and efficiency. Three software experts and one master graduate in communication individually evaluated the intervention based on the list of heuristics. The user-based test included a think-aloud procedure. Two patients and two healthy people were asked to perform a set of consecutive tasks, which represented the major functionality of the intervention. Simultaneously, the subjects were encouraged to verbalize their thoughts [45]. Participants of both tests were asked to suggest improvements about the issues they came across.

The main credibility and usability issues that were identified are summarized in Table 1. Changes to these issues were incorporated before the release of PatientTIME apart from one. The illustrative pictures of patients in the layout were evaluated by the users as too positive. However, because we wanted to present a positive and encouraging context, we kept these pictures.

**Table 1** Summary of identified credibility and usability issues

Identified issues		Processed changes
Credibility	Information about collaborating parties, help function, and privacy issues is missing / unclear.	An extra information page was added with separate tabs containing information about collaborating stakeholders, introducing members of the working group, explaining privacy issues, and explaining the scientific context. A separate 'help' function was highlighted with contact details, frequently asked questions, and a project summary.
	Print function QPS unclear and use of the agenda not clear	The agenda was made accessible on the home page, corresponding text was changed, and buttons were highlighted. The print function of the QPS <sup>a</sup> was highlighted.
Navigation	Location and additional text related to 'log-in' button is confusing. It is not always clear which elements are 'buttons'. Not always clear where you are in the website.	The consistency in color use and type of buttons improved, more contrasting colors were used when mouse-over, headings of active pages remain high- lighted and stand out more comparing to the headings of inactive pages, the home pages present instructing messages to the user about the project status.
	Some texts are too formal. Some inconsistency in use of terms / jargon.	Textual changes were made.
Layout	Illustrative pictures too positive / happy.	Another way to present the video diaries was developed, the video archive was removed and its function was incorporated in the video page.
	Unclear presentation of the selection of video clips. It is not clear what the content of the 'video archive' is or will be.	

<sup>a</sup> QPS: question prompt sheet

### **3.3.6 Development of Evaluation Plan (Step 5)**

The goal of the fifth step was to develop an evaluation plan to examine the effects of the intervention. Decisions regarding the evaluation were partly stipulated in the research protocol, which proposed a randomized controlled trial (RCT) in which participants are randomized into the intervention group (with access to PatientTIME) and control group patients (without access to PatientTIME).

While working out the RCT protocol, practical issues like recruitment and patient information were discussed with the research partners and questionnaires were developed in collaboration with them. One patient research partner and one patient service user were asked to pre-test the developed questionnaires with a think-aloud procedure. Their feedback focused mainly on questions initially formulated as too formal or medical jargon that was unclear.

The involvement of prospective participants (ie, patient service users) in the RCT was planned on different levels. Both intervention and control group participants were asked to participate for a maximum of three consultations and they were both asked to fill in questionnaires delivered via their personal account. On the lowest participation level, participants are provided with information and asked to complete questionnaires. On a second level, they are encouraged to verbalize their ideas and input with regard to the study design to inform decisions taken by the working group. Last, a random subset of patients in the intervention group is encouraged to audio record and upload their consultation(s) on their secured PatientTIME account. This pilot was designed for the purpose of evaluating the playback option as well as to be analyzed by the researchers on their actual participation during their consultation.

The developed RCT protocol was audited with external experts to evaluate privacy issues and the exchange of online information and to assess and reduce possible risks. Because of the juridical, technical nature of the audit, we did not include patients in this audit. The Medical Ethical Committee of the Radboud University Nijmegen Medical Centre evaluated the RCT protocol and concluded that following the Dutch Medical Research Involving Human Subjects Act, the study did not require ethics approval. The RCT (registered in the Netherlands Trial Register, 3779) started in 2013 and the first results are expected to be available in 2015.

### **3.3.7 Development of Implementation Plan (Step 6)**

The goal of the last step was to design an implementation plan that would guide the transfer of the intervention to a publicly available online tool. Contrary to the

detailed evaluation plan, the implementation plan was a rough setup of actions that were guided by and adapted to decisions made in previous steps. To increase the chance of a successful implementation and adoption, the involvement of patients and Hematon in the planning and execution of the actual implementation started as early as the project planning. In the preparatory step, the board of Hematon was asked to help thinking about the valorization of the research results. In this way, we aimed to divide responsibilities at an early stage and awareness was created about the upcoming intervention.

Hematon wanted to make developed materials available for all their members and other patients. As a result, an agreement was established noting that after research is finalized, Hematon would become responsible for hosting the tool. Subsequently, during the development of the intervention and evaluation plan, several meetings were planned with our software developer and the webmasters of Hematon. In consultation with them, we aimed to develop materials that were not only usable for the secured trial setting, but could easily be transferred to a publicly available tool. Both patient research partners will be actively involved in the actual transfer of the intervention.

This transfer is not within the scope of this paper and will be done when the RCT proves to be acceptable, usable, and efficient. Lessons learned from the evaluation will be used to optimize the intervention before implementation.

## **3.4 Discussion**

### **3.4.1 Principal Findings**

In the PatientTIME project, patients were given the opportunity to actively participate in the development of an online communication intervention with corresponding evaluation and implementation plan. In conformity with previously publications, the cooperation with patients brought valuable insights and appeared to influence many decisions made [46,47]. By combining patient participatory methods with a theoretical protocol, we aimed to create a bottom-up inspired development procedure. We encountered both facilitating elements, as well as obstacles in this approach.

### **3.4.2 Facilitators to Participatory Development**

The combination of evidence-based and patient participatory methods did assist us in involving patients. The structure of the IM framework helped us choose when to

involve patients, while the idea of participation ladders and user-centered design thinking inspired us in how to involve patients.

The involvement of patients on different levels appeared to be useful and practical. The patient research partners ensured a continuous patient-centered view, while the patient service users were able to give fresh new insights on different protocol steps.

Both Hematon as well as the research partners were involved from the very beginning of the project as a result of the preparatory planning step. We experienced this as a precondition to creating a continuous patient-centered view. Their early involvement supported the participation of patient service users and it gave the opportunity to discuss possible valorization of results at an early stage.

Another facilitating aspect was the attitude of the participating patients. They all seemed to recognize why the intervention was developed. This appeared to be a driving force behind their motivation to participate. Attracting engaged patients may be a precondition to creating a successful patient-centered approach.

### **3.4.3 Obstacles to Participatory Development**

The recruitment and involvement of patients was a time-consuming part of the project. In some steps, we could have benefited from more involved patient service users (especially the intervention development step), but time constraints prevented us from doing so. The extent of patient involvement relates to the amount of time available to execute the project. However, we think time constraints should not be a reason for limited participation.

Flexibility in terms of planning and setup seemed a precondition to including the perspectives of the (seriously ill) patients. For example, during the needs assessment, some patients were too ill to attend a focus group session. An interview at their home gave us the opportunity to incorporate their experiences as well. Considering the illness of the targeted patients, we think the extent of involvement of service users should be evaluated per protocol step.

Flexibility also appeared to be a key concept in incorporating patients' viewpoints and experiences in the defined research proposal. In the current study, a research proposal defined certain decisions, for example, the intervention would be delivered online and the evaluation of the effects would be tested in an RCT. Although the proposal was built on previous research and experiences, these decisions were made before the targeted patients could be consulted (see Future Research).

#### **3.4.4 Future Research**

While there is a desire for more patient participation in research, it seems to clash with strict research proposals and protocols that need to be approved before the start of a project. Perhaps researchers should involve (ex-) patients in the design of such documents. However, this still does not give the required flexibility to adapt a project to the input of patients, gathered along the way. Patient participation in research projects that include design activities requires methodologies that allow the dynamics of design (eg, by patient input) to influence the process. Intervention mapping can be a guiding method, unless it is bounded to a strict predefined proposal. Participatory Learning and Action Research or Design Inclusive Research might be interesting alternative methodologies [48-50]. Funders also should evaluate the extent of detail they request in proposed projects and how this might restrict the extent of (true) influence patients can have.

Considering the evaluation of online interventions and the necessary flexibility to incorporate patients' input, it might be interesting to study other perhaps more flexible evaluation methods than an RCT. A longitudinal study where intermediate results can be used to optimize the intervention during the test phase might be an interesting alternative. Furthermore, some patients might have a strong preference for using or not using technology. In the case of strong preferences, results may be biased when using a regular randomized controlled trial. Within preference trial designs, this bias is dealt with by the fact that patients with strong preferences for either intervention will get the intervention they prefer. Only those without explicit preference are randomly assigned to either the intervention or the control group [51].

#### **3.4.5 Limitations**

A limitation of the applied method is that the participating patients represent a self-selected convenience sample as involved patients voluntarily signed up to contribute to the study. This could have led to a biased view of a more empowered group of patients. In general, the possibility of having a biased group of participants in a participatory development approach is evident, as one needs to find patients that are interested in cooperating. On the other hand, one wants to develop an intervention that reaches out to the whole targeted population. This advocates the use of different participation levels and creative solutions to attract and/or select patient service users to capture a broad view of experiences.

Similar to other studies [52], in the current study the IM framework was not



applied in a linear way as proposed, which can be argued as a potential limitation. However, a design process rarely follows a parallel execution process and, especially because the aforementioned flexibility was required, we think it does not have to affect the quality of the developed products.

#### **3.4.6 Conclusions**

Involvement of patient research partners in combination with patient service users can inspire and guide the evidence-based intervention mapping protocol. Early involvement, involvement on different levels, and flexibility in terms of planning and setup seem to be preconditions to create a bottom-up inspired development procedure with (seriously ill) patients. Further research is necessary to find out if a more patient-centered approach improves the implementation and uptake of eHealth interventions.

#### **Acknowledgments**

We are grateful to all patients for their involvement, Hematon representatives for their advice and help with patient recruitment, and the Alpe d'HuZes program of the Dutch Cancer Society for its financial support.

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# 4

## The impact of watching educational video clips on analogue patients' physiological arousal and information recall

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*Published as:*

van Bruinessen IR, van den Ende IT, Visser LN, van Dulmen S. The impact of watching educational video clips on analogue patients' physiological arousal and information recall. *Patient Education and Counseling*, 2016 Feb; 99(2):243-9.

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## Abstract

**Objective:** Investigating the influence of watching three educational patient-provider interactions on analogue patients' emotional arousal and information recall.

**Methods:** In 75 analogue patients the emotional arousal was measured with physiological responses (electrodermal activity and heart rate) and self-reported arousal.

**Results:** A moderate increased level of physiological arousal was measured but not too much to inflict emotional distress. Recall of information was within the pursued range.

**Conclusion:** Hence, physiological arousal is not expected to hinder the goals we pursue with our online intervention.

**Practice implications:** Still, developers and researchers should remain attentive to the self-reported (conscious) and hidden (subconscious) emotions evoked by the content of educational video clips presented in self-help interventions. A moderate increased level of arousal is preferred to increase the learning capacity. However, too much arousal may decrease the learning capacity and may cause distress, which should obviously be avoided for ethical reasons.



## 4.1 Introduction

The complex and emotionally loaded nature of communication in oncology care challenges health care professionals (HCPs) as well as patients. Reaching effective communication is of great importance for optimal care and it supports patients in coping with their disease and disease-related concerns [1–4]. So far, research and training in communication competences have primarily been focused on HCPs, but to establish effective communication both parties need to participate actively [5]. This shift, from provider-centred to a more relationship-centred interaction style, has relevance for patients' conversational contribution [6–8]. To support patients in their communication, various educational tools have been developed, such as fact sheets, question prompt sheets and brochures [9].

With the rise of web-based initiatives aiming to support and empower patients, educational video clips provide additional opportunities. Communication behaviour and desired attitudes can be modelled in video clips, with proven instructional effectiveness [10,11]. Patient activation programs that studied the effect of modelled communication behaviour show promising results on patient participation in medical communication and satisfaction [12–15]. The educational clips used in these studies are based on narratives in which the modelled communication behaviour and strategies are embedded. Narratives provide illustrative examples of patients' experiences. Identification with narrative characters has shown to be important to recall the central information of educational clips [16]. This promotes the use of realistic simulations. Yet, the context of the communication and identification with the (video) patient can also evoke emotional arousal [17]. This is especially evident in oncology care. Web-based self-help interventions are mostly used without the feedback or presence of a professional. Therefore it is important to investigate the emotional impact of the educational clips thoroughly [18]. A moderate increased level of arousal caused by increased attention is appropriate. However, too much arousal should obviously be avoided for ethical reasons. Moreover, for the educational purpose it is important to investigate if the central message of the video clip is remembered as intended.

We recently developed a pre-visit computer-tailored intervention (PatientTIME) aimed at increasing patient participation in oncology care [19]. Patients can use this intervention to prepare their medical consultations. The central source of information is provided via educational clips of simulated physician–patient encounters. The provided selection of clips is individually tailored to previously identified communication barriers (e.g. asking attention for concerns, checking

information) [20]. In the video clips different communication strategies are demonstrated during simulated encounters. The goal of the video clips is to give patients examples of communication strategies, helpful to overcome their communication barriers. Correct recall of the provided information is important because it is a prerequisite for patients who have the intention to apply the modelled behaviours in the consultation room. Yet, if the video clips evoke too much emotional arousal this goal might be missed.

Emotional arousal can be measured in different ways. Before and after watching video clips, the self-reported emotional state can be measured with questionnaires. This method is relatively easy to apply and frequently used to measure emotions. However, emotions also involve subconscious reactions, which may be overlooked by the participant. These reactions are not reflected in self-reported data, but can be indexed by continuously monitored physiological responses [21]. Physiological responses are important components of emotional experiences [22]. Moreover, they are expected to influence the recall of provided information [23]. In the current study we first investigated analogue patients' emotional arousal evoked by watching educational clips, using both self-reported and psychophysiological measures. Second, we evaluated whether the modelled communication strategies were remembered as intended (the cognitive experience).

## **4.2 Method and materials**

### **4.2.1 Design**

An experimental study was set up whereby participants watched three short video clips selected from the PatientTIME intervention. In the video clips a video patient demonstrates different communication strategies during an oncology consultation. Emotional arousal was measured before, during and after watching the video clips. Recall of information was measured after watching the video clips.

### **4.2.2 Participants**

Men and women (>18 year) with a good understanding of the Dutch language were recruited via online research advertisements and via leaflets at libraries and supermarkets. Applicants with a history of a heart disease were excluded as this could influence the measured heart rate (HR) signal. People with malignant lymphoma were also excluded because they were invited to the overarching study, which focused specifically on this target group. Participation was voluntary and

subjects obtained a s10 gift voucher and the opportunity to have their travel expenses be reimbursed.

For ethical reasons we did not include patients for this experiment. Instead the analogue patient approach was used. Analogue patients are healthy participants who are instructed to identify with the video patient and assess the video clips as such. Recent studies conclude that this method is a valid alternative for clinical patients in communication research [24,25]. Patients also seem to have similar psychophysiological responses when they watch their videotaped consultation compared to when they are taking part in that consultation [26].

#### **4.2.3 Stimuli**

Three short video clips were selected from the online patient communication intervention PatientTIME [19]. Each clip centres around a communication barrier, which the targeted patients with malignant lymphoma have indicated to experience as difficult in a previous study [20]. The video-patient is a 50 year old women diagnosed with malignant lymphoma. In each video clip she demonstrates best practices of different communication strategies (Table 1).

#### **4.2.4 Measures**

##### **Background characteristics**

Background characteristics (e.g. age, gender, education) were gathered before the experiment.

##### **Quality check**

The quality of demonstrated video clips may influence the recall of information. To validate the quality of the video clips, participants were asked to assess the style, structure and understanding of the video clips by means of twelve questions on a seven point Likert scale. The average score of the twelve quality questions was calculated after checking the internal validity. The internal consistency of the 12 quality items was good (Cronbach's  $\alpha = 0.88$ ).

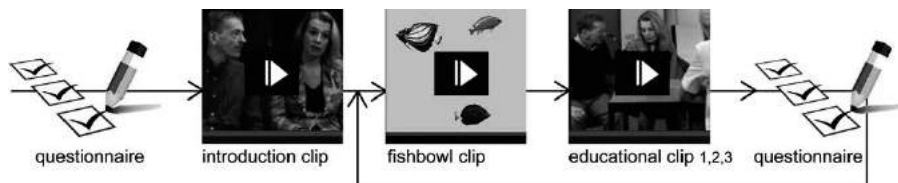
Additional to this quality check, participants were asked to what extent they could identify with the video-patient (seven point Likert scale, 1 = not at all, 7 = very much).

**Table 1** Characteristics of the educational clips

Topic	Duration (s)	Related communication barrier	Central information, i.e.; demonstrated communication behaviour (best practice)
Receiving bad news	59	Being overwhelmed by emotions/not able to hear what is explained	<ul style="list-style-type: none"> <li>- Interrupting the doctor/asking to pause</li> <li>- Indicating that the explanation was not heard</li> <li>- Showing emotional need for support</li> </ul>
Explaining worries and concerns	62	Not getting attention for worries and physical complaints	<ul style="list-style-type: none"> <li>- Explaining/emphasizing physical complaints and worries</li> <li>- Asking for a physical examination</li> <li>- Prioritizing questions/things to discuss</li> </ul>
Checking and understanding complex information	79	Not understanding the given information	<ul style="list-style-type: none"> <li>- Taking notes</li> <li>- Asking for clarification</li> <li>- Checking if the information was understood correctly</li> </ul>

### Self-reported arousal

The pre- and post-self-reported momentary anxiety was assessed with the validated Dutch state version of the STAI (State–Trait Anxiety Inventory, 10 four point Likert scaled items) before and after watching the video sequence (Fig.1) [27–29]. Total scores range from 10 to 40, whereas 17 is considered normal, 24 is an acute anxiety response to a stressful situation [27]. The self-reported arousal was corrected for missing values. As suggested by Spielberger [27], inventories missing two items or less were retained for analysis and a value of two was assigned to the missing items (two inventories had one missing) [27]. Internal consistency of the STAI inventories was high ( $\alpha_{pre} = 0.88$ ,  $\alpha_{post} = 0.90$ ).

**Figure 1** Video sequence

## Physiological arousal

Emotions, stress and thoughts can activate the autonomic nervous system (ANS), which increases physiological arousal [23,30]. The ANS consists of the sympathetic nervous system (SNS) and the parasympathetic nervous system (PNS). SNS activation can be monitored by the EDA [22,30]. The electrodermal activity (EDA) and heart rate (HR) are the most frequently used measures to monitor the physiological arousal [22].

The electrodermal system is the most responsive system when studying the reaction of subjects to stimuli that elicit anxiety. When a participant is at rest, it is common for the skin conductance level (SCL) to change gradually. Emotional arousal may increase the SCL; i.e. the skin momentarily becomes a better conductor of electricity. After an increase in conductivity, the level gradually decreases again. The typical range of the SCL is between 2 and 20 mS, but wide variation is seen between different subjects and even within the same subject [31].

Besides measuring these tonic changes, phasic changes (spikes) can be marked in an electrodermal signal. This skin conductance response (SCR) is a characteristic electrodermal response, usually occurring 1–3 s after a novel stimulus is introduced. Phasic SCRs are related to attention. When a subject is at rest, non-specific spikes occur typically between 1 and 3 min<sup>-1</sup> [31].

Compared to the EDA measures, HR is different because it reflects a combination of sympathetic and parasympathetic activity [32]. Cognitive challenges, like remembering communication strategies, can induce changes in the cardiovascular response [33,34].

In the current study these physiological responses were measured before and during video watching. Via the BIOPAC MP150, the SCL was measured in micro Siemens (mS), the SCR in spikes per minute (spm) and the HR in beats per minute (bpm) with disposable gel finger electrodes. A Windows 7 operated computer collected the physiological data with Acknowledge 4.1 and Observer XT 10.0. In Observer the physiological data were synchronized with the video sequence.

In Acknowledge 4.1 the EDA and HR signals were prepared to transfer to STATA 13.0. To eliminate high frequency noise of the EDA signal, a low pass filter was applied (cut off frequency 1 Hz). Spikes in the EDA signal were detected using 0.05 Hz High Pass filter (baseline estimation window width 5 s, threshold level 0.05 mS).

The mean SCL and the amount of spikes per video clip were exported for analysis. The HR data were manually checked for noise. Six HR signals did not

represent a typical rhythmic signal and were excluded from analysis. Too much or too sudden movements of the hand or failure in the electrodes may explain this error. The facilitator confirmed the first explanation. The mean HR per video clip was exported for analysis.

Because each individual has a different, physiological baseline activity and reactivity pattern, measures were compared to individually established baseline scores.

## **Recall**

Recall of information was assessed with an open question (“what do you remember from the video clip you just saw?”) and a prompted recall question (“what does the patient do to communicate adequately with the doctor”). A codebook with four categories (0 = no items correctly recalled, 3 = all items correctly recalled) was used to assess how many strategies (Table 1, column 4) were recalled correctly. Two researchers independently coded the recall answers of 25 of the 75 participants. The interrater agreement was substantial (Cohen’s  $k = 0.71$ ) [35]. Subsequently, one researcher coded the remaining answers and in case of uncertainty, answers were discussed with a second researcher.

### **4.2.5 Procedure**

Participants were welcomed and asked to wash their hands and wrists as a preparation for the EDA and HR measurement. The facilitator explained the experimental procedure and asked the participant to watch the video clips while identifying with the video patient. In other words, they were asked to act like an analogue patient [24]. Additionally, the facilitator explained that the video clips demonstrated parts of a medical encounter between a doctor and a cancer patient.

After signing the informed consent form, participants were asked to fill in socio-demographic questions and the STAI. Then they were prepared for the EDA and HR measurement by attaching electrodes to the wrist and two fingers of the non-dominant hand. Before starting the video sequence (Fig. 1), the facilitator summarized the main instructions and left the participant alone to watch the sequence. During the experiment the facilitator observed the participants with video, to start the clips at the right moment and to check if the participant was not moving too much.

To increase participants’ empathic involvement, the video sequence started with an introduction. This video clip displayed the video patient introducing herself and

explaining her medical history (51 s). The baseline physiological measurements were taken during a neutral fishbowl clip (30 s), which was shown after the introduction clip. Then the first educational clip was shown. After this first educational clip the participant was asked to complete the recall questions. This procedure was repeated with the second and third educational clip. Time between viewing the clips was approximately 5 min.

Participants were continuously physiologically monitored. To counterbalance the order effect, the computer randomly assigned participants to one of the six possible orders of the three educational clips. At the end of the sequence, participants were asked to complete the STAI again and the evaluation questions. After the experiment they were debriefed by explaining the overarching goals of the experiment. The whole procedure lasted approximately 30 min and was tested and optimized through five pilot sessions with five participants, which were left out of the current analyses.

#### **4.2.6 Analysis**

Data were analysed with STATA 13.0. Descriptive statistics were used to describe the background variables, the arousal scores and the recall scores. A paired t-test was used to compare the self-reported arousal scores before and after the experiment.

The physiological arousal scores were analysed with linear regression to control for the baseline measures and the possible effect of socio-demographic variables. To analyse differences in physical arousal levels between the three video clips, paired t-tests were used for the SCL and HR. The Wilcoxon signed rank test was used to analyse SCR, because this data demonstrated a skewed distribution.

### **4.3 Results**

#### **4.3.1 Background characteristics**

The participants were for the greater part highly educated and relatively young. The overall quality of the video clips was on average assessed with a 5.0 on a seven point Likert scale ( $s = 0.96$ ).

Participants indicated that they could identify relatively well with the video patient, 4.7 on a seven point Likert scale ( $s = 1.25$ ) (Table 2). No differences in reported capacity to identify with the patient were found between groups characterised by age, gender, level of education, experience with cancer or with medical encounters in oncology care.

### 4.3.2 Self-reported arousal

Participants' self-reported arousal at post-measurement was not significantly different from their score before watching the video sequence ( $p = 0.14$ ). Before the experiment 9 participants and after the experiment 10 participants reported a score of 24 or higher, indicating an acute anxiety response (Table 2). Four out of the ten participants that rated their anxiety as high in the posttest, also scored high on the pretest.

**Table 2** Sample characteristics

Characteristics participants	n = 75	$\mu$	$\sigma$	Min	Max
Age		33.1	13.4	18	66
		N	%		
Gender	Male	31	41		
	Female	44	59		
Education	Low	3	4		
	Medium	10	13		
	High	62	83		
Relation to cancer	No	22	29		
	Yes, relative	51	68		
	Yes, myself	2	3		
Experience with consultations in oncology care	Yes	5	7		
	No	70	93		
Self-indicated health status	Excellent	10	13		
	Very good	31	41		
	Good	30	40		
	Average	4	5		
	Poor	0	0		
<b>Quality assessment video clips (range 1-7)</b>		<b><math>\mu</math></b>	<b><math>\sigma</math></b>		
Quality measure total score W2–W13	n = 75 ( $\alpha$ 0.88)	5.01	0.96		
Identification measure “(How well could you identify with the video patient?)”	n = 74	4.68	1.24		

- Table 2 continues -



- Table 2 continued -

STAI* (scale 1–4)		$\mu$	$\sigma$	Min	Max
STAI pre	n = 75 ( $\alpha$ 0.88)	17.07	4.57	10	32
STAI post	n = 75 ( $\alpha$ 0.90)	17.88	5.02	10	36
Characteristics participants		$\mu$	$\sigma$	Min	Max
Information recall (range 0-3)		$\mu$	$\sigma$		
Clip 1 (receiving bad news)	n = 75	1.87	0.68		
Clip 2 (explaining worries and concerns)	n = 75	2.27	0.76		
Clip 3 (checking and understanding)	n = 75	2.45	0.72		

\* t-test for paired samples;  $p = 0.14$

#### 4.3.3 Physiological arousal

The mean SCL was significantly increased during all three educational clips in comparison with baseline. There were no significant differences in SCL between the three video clips. When controlling for socio-demographic variables in the regression analysis, gender appeared to be a significant confounder in clip 2; women had less increased SCLs compared to men.

The level of education appeared to be a significant confounder in clips 1 and 3. In clip 1 it suggested that a higher level of education resulted in a more increased SCL. In clip 3 the opposite was suggested.

Changes in SCR en HR compared to baseline were minor. The SCR during each educational clip was on average slightly lower in comparison to baseline. This difference was small but statistically significant in video clips 2 and 3. No significant differences were found in SCR between the three video clips. During video clip 2 the HR was significantly lower compared to baseline (D1 bpm) and in this video clip the HR was lower compared to video clips 1 and 3 (Table 3 and Fig. 2).

#### 4.3.4 Recall

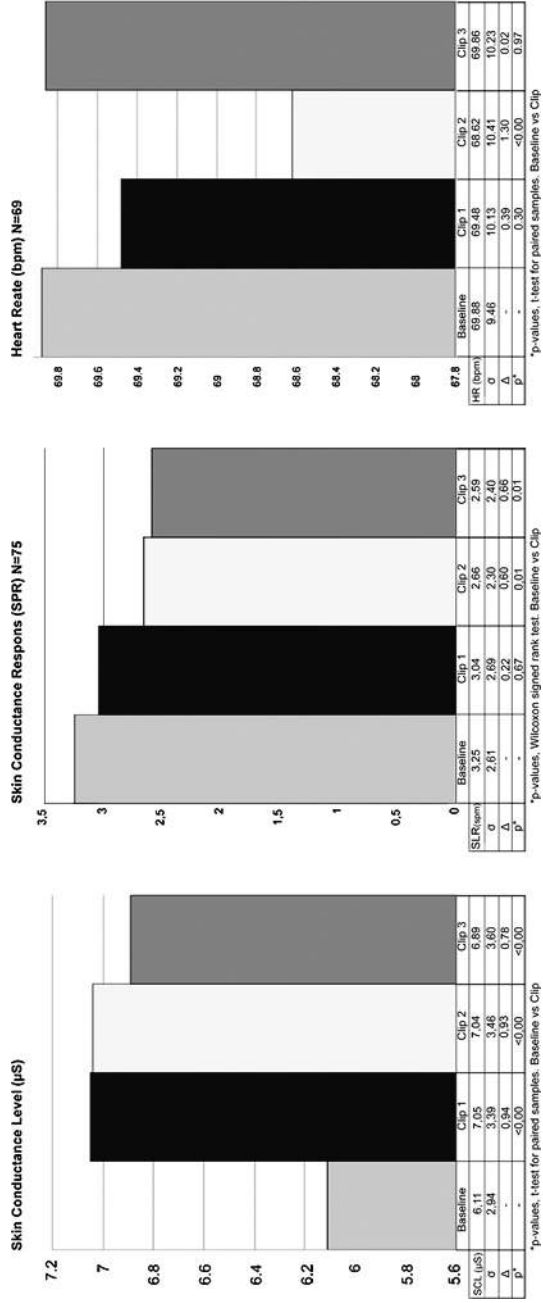
The information recall for video clip 1 (receiving bad news) was significantly lower than the recall for video clip 2 (explaining worries and concerns) and video clip 3 (checking and understanding), both  $p < 0.00$ . The information recall for video clip 2 was lower compared to video clip 3, but this differences was not significant ( $p = 0.08$ ) (Table 2).

**Table 3**      Physiologic arousal

		SCL (μS) n = 75	ΔSCL	SCR (spm) n = 75	ΔSCR	HR (bpm) n = 69	ΔHR
Baseline	μ (σ)	6.11 (2.94)		3.25 (2.61)		69.88 (9.46)	
Clip 1	μ (σ)	7.05 (3.39)	.94 (1.72)	3.04 (2.69)	-.22 (2.29)	69.48 (10.13)	.39 (3.18)
	p <sub>-</sub> <sup>*</sup>	p < 0.00		p = 0.67 <sup>**</sup>		p = 0.30 <sup>*</sup>	
Clip 2	μ (σ)	7.04 (3.46)	.93 (1.70)	2.66 (2.30)	-.60 (2.10)	68.62 (10.41)	-1.3 (3.4)
	p <sub>-</sub> <sup>*</sup>	p < 0.00		p = 0.01 <sup>**</sup>		p < 0.00 <sup>*</sup>	
Clip 3	μ (σ)	6.89 (3.60)	.78 (1.52)	2.59 (2.40)	.66 (2.11)	69.86 (10.23)	-.02 (3.33)
	p <sub>-</sub> <sup>*</sup>	p < 0.00		p = 0.01 <sup>**</sup>		p = 0.97 <sup>*</sup>	

<sup>\*</sup>    p-values, t-test for paired samples: baseline vs clip.

<sup>\*\*</sup>   p-values, Wilcoxon signed rank test: baseline vs clip.



**Figure 2** Physiologic arousal

## 4.4 Discussion and conclusions

### 4.4.1 Discussion

In the present study the impact of watching educational video clips, encompassing patient–provider interactions in oncology care, was investigated on the emotional arousal and recall of analogue patients.

The self-reported arousal measures did not indicate an increase in anxiety. In conformity with the results from a comparable study [36], we did not find correlations between the self-reported arousal and the SCL. However, others did find a relationship between subjective and physiological measures [22,30]. Compared to baseline, the mean SCL was significantly increased during all three educational clips, indicating an increased arousal level. The changes in SCR and HR were minor.

The increase in SCL may indicate emotional arousal caused by the content of the educational clips. The SCR at baseline was slightly higher to what literature considered as normal (1–3 min<sup>-1</sup>) [31]. This may indicate that taking part in the experiment induced some arousal and that participants were alert when starting the experiment. Another explanation is that the relatively short baseline measurements were influenced by carry over affects (see Section 4.2). While the experiment continued, the SCR decreased slightly, but remained close to the 3 spm. Habituation to the occurrence of the experiment may be an explanation for the decrease; i.e. participants may have started to anticipate to novel, but comparable stimuli in de video clips.

The mean HR did not increase during the educational clips. In one of the video clips a significant HR decrease was measured, but clinically this does not seem to be a relevant difference (1 bpm). To compare, in healthy untrained individuals the HR increases by 15 bpm one minute after standing up from a sitting position [37]. The presented stimuli may have been not ‘extreme’ enough to influence the HR, which is different from the EDA measures, controlled by the sympathetic and parasympathetic activity.

On average per video clip, two out of three demonstrated communications strategies were recalled correctly. Because per video clip all three strategies relate to the same communication barrier, we consider this score as sufficient for the educational purpose. The differences in recall scores may be explained by the differences in the emotional nature of the discussed information. The lowest recall scores were found in clip 1. This clip represents a fragment of a bad news

consultation and an emotionally overwhelmed video patient. The impact of the discussed information may have distracted from the demonstrated communication strategies. In clips 2 and 3 the video patient demonstrates a more active communication style. This may have drawn the attention more to how things were said instead of what was being said. On the other hand, the physiological data do not demonstrate a significant difference in emotional reaction between the three clips. If the differences in recall resulted from the emotional content, we would expect to see this also in the physiological data, so further research is necessary to clarify the recall differences.

To conclude, the recall scores and the absence of strong physiological effects are positive, having the educational purpose and the autonomous use of the video clips in mind.

#### **4.4.2 Limitations**

Several limitations are related to the chosen method and measures. First, a limitation of the study design was the duration of the baseline measurement. The SCL decreased during the baseline measurements and did not seem to have levelled out at the end of the baseline assessment. The measurements during the neutral clips shown prior to the second and third video clip demonstrated a similar pattern. This indicates that these neutral clips might have been too short to return to baseline. This may have led to a negative bias in the effect looking at the delta scores and also enlarged the chance of carryover effects.

Second, the interpretation of physiological measures is not unambiguous. Novel stimuli can induce strong responses while habituation to a situation will level out the magnitude of responses [38]. Also, non-specific processes are always active (bodymovement, thoughts, background noises, etc.). Especially the SCL is highly sensitive and responds to many other stimuli [31]. Also the interpretation of changes in the HR is challenging. Excitement is known to increase the HR, concentration and attention can slow down the HR [39]. In the current study, participants were asked to identify with the video patient and they knew that they had to complete questions afterwards. This focus may have counter- balanced a possible increase in HR due to excitement.

Third, a relatively large amount of participants (9) reported an acute anxiety response before the start of the experiment. A methodological limitation may explain these remarkable outcomes. The instructions given before the experiment included the explanation about identifying with the video patient. The self- reported

anxiety questionnaire was completed after this instruction. Some participants may have completed the STAI while imagining how they would feel awaiting for an oncology consultation. Another explanation is that for some patients the experiment in itself and awaiting the first video clip was quite arousing. This would explain the high variance and the high scores prior to the experiment. Four participants that rated both pre and posttest above the threshold may be high trait anxious. We could not control for this as we did not measure the trait anxiety of the participants.

Fourth, the analogue patient paradigm is a validated method in communication research [24,25]. However, clinical patients may experience the video clips differently, because of various reasons (e.g. they have to deal with uncertainty, they have built a relationship with their physician, they have more knowledge about possibilities and consequences). Further research should evaluate how clinical patients experience the video clips or to what extent the paradigm limits generalizability.

At last, the relatively high level of education of the participants may have positively influenced the recall scores and makes it harder to generalize these results.

#### **4.4.3 Challenges for further research**

To get more insight in the effects of (sub) conscious emotions in communication research, the use of physiological data can be a complementary method to self-reported data [40]. However, this fairly new combination of research disciplines raises a variety of methodological challenges [36,40,41]. There are different ways to measure, compare, analyse and interpret physiological responses, which makes it difficult to compare different studies. As a result of the lessons learned in the current experiment, a few challenges for future research are highlighted.

First, considering the large variety in individual reactivity, an accurate and lengthy baseline measurement seems essential. The challenge is to adapt the baseline measurement to the stimuli under study to avoid noise components as much as possible. During the baseline measurement in the present experiment, the participants were not given a task comparable with the task during the video clips under study (identify with the video patient), so we could not control for this. For the purpose of this study this was not an issue, but for future research it may be interesting to control for possible task-related arousal. Second, the type and combination of physiologic measures needs to be chosen deliberately.

In the current experiment we chose to compare the mean SCLs and the total amount of SCRs. The rationale for this choice was the relatively short educational clips under study, combined with the fact that we were interested in the overall experience. This method does not identify specific arousing moments in the educational clips. If more detailed information is required about e.g. specific communication utterances, analysing the slopes of the SCL [41] or searching for SCR patterns will give additional information.

Third, recent studies show that each emotion evokes a specific physiologic response pattern [42,43]. Fear and sadness were the predominant emotions in the presented educational clips. To accurately interpret physiologic data, it may be helpful to distinguish these emotions. In line with this, the self-reported emotional arousal measure should also be able to distinguish different emotions. The Self-Assessment Manikin (SAM, a non-verbal pictorial inventory), the Profile of Mood States (POMS, a self-rating scale consisting of 65 adjectives measuring 6 identifiable affective states) or a Visual Analogue Scale (VAS, 0–100 analogue scale) may be interesting measures to consider [44–46].

#### **4.4.4 Conclusions**

In the current experiment analogue patients' emotional arousal and information recall while watching educational patient-oncologist interaction video clips were investigated, to ascertain that (1) the clips would not inflict emotional distress (ethical reason), and (2) the central information would be remembered as intended (educational purpose).

The educational clips evoked some arousal, but not too much to inflict emotional distress. Recall scores were sufficient for the educational purpose of the clips.

In the development of educational video clips aiming to support and empower patients, a realistic setting and story on the one hand, versus the (emotional) context on the other hand, may need to be well balanced. Developers and researchers should be aware of the conscious and subconscious emotions evoked by the content of educational clips presented in online self-help interventions.

#### **Acknowledgements**

We are grateful to all participants for their kind co-operation. We thank Alpe d'HuZes of the Dutch Cancer Society for their financial support.

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# 5

## When patients take the initiative to audio-record a clinical consultation

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*Submitted as:*

van Bruinessen IR, Leegwater B, van Dulmen S. When patients take the initiative to audio-record a clinical consultation.

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## Abstract

**Objective:** to get insight into professionals' current experience with, and views on consultation audio-recordings made on patients' initiative.

**Method:** 215 Dutch health professionals (123 physicians and 92 nurses) working in oncology care completed a survey inquiring their experiences and views.

**Results:** 71% of the respondents had experience with the consultation audio-recordings. Health professionals who are in favour of the use of audio-recordings seem to embrace the evidence-based benefits for patients of listing back to a consultation again, and mention the positive influence on their patients. Opposing arguments relate to the believe that is confusing for patients or that it increases the chance that information is misinterpreted. Also the lack of control they have over the recording (fear for misuse), uncertainty about the medico-legal status, inhibiting influence on the communication process and feeling of distrust was mentioned. For a considerable number of respondents, these arguments and concerns were reason enough not to cooperate at all (9%), to cooperate only in certain cases (4%) or led to doubts about cooperation (9%).

**Practice implications:** the many concerns that exist among health professionals need to be tackled in order to increase transparency, as audio-recordings are expected to be used increasingly.

## 5.1 Introduction

While health professionals are responsible for facilitating the consultation process, patients are increasingly expected to be informed participants and to be able to make conscious decisions [1]. Clearly, the complex nature of medical encounters and the often vulnerable and emotional position of patients make this role challenging for them, which is evident in oncology care [2-4]. In 2007, Epstein and Street stressed the need to support patients in the communication process [5]. Giving patients an audio-recording of the consultation to replay, has proven to be an effective approach in this context. Studies in the oncology setting reveal that patients highly value audio-recordings, the majority benefit from listening to the recordings, and they provide support in achieving effective medical communication [6-10]. Moreover, it improves information recall [11-13], gives a clearer understanding of treatment options [14, 15] and induces more active engagement in treatment decisions [15, 16].

Despite these benefits, routinely providing audio-recordings to patients has not yet become common practice in oncology clinics [6, 8]. Practical issues like funding and logistics, as well as health professionals' antagonistic views seem to impede implementation [17, 18]. However, current developments have led to a resurgence in the use of audio-recordings in clinical practice, but from a different perspective. Whereas previously the health professional facilitated and provided the recording, now patients take the initiative. Smartphones and tablets enable patients to make audio-recordings in an easy and accessible way and in the Netherlands, patient associations have started to encourage patients to record their clinical consultations. Online discussions between health professionals reveal that (also in other countries) professionals are confronted with these developments in clinical practice [19-21].

From an organizational perspective, the administrative support, logistics, and financial resources may be simplified when patients take the initiative to record the clinical consultation, rather than health professionals. It may be far easier to obtain audio-recordings across medical specialties (in the case of severe or chronic conditions) when the patient is in control. This approach also fits with the increased focus on patient engagement and transparency in health care. However, the use of consultation audio-recordings made on the initiative of patients, will only be feasible when both parties (health professionals and patients) endorse this new approach. But what are the opinions of health professionals on being recorded on patients' initiative? To our knowledge, other research in this context is focused on shared

personal experiences and case studies that mainly describe the covert recording of clinical encounters [19-21].

To follow the developments in the use of consultation audio-recordings and to find out how they can advance patient-professional communication in oncology care, we set up an explorative study. In this study we aimed to get insight in the current experiences of Dutch health professionals with consultation audio-recordings and their views, that may influence the use of the recordings made on the initiative of patients.

## **5.2 Method**

### **5.2.1 Participants and design**

An online survey was set up, based on previous research related to consultation audio-recordings [17]. Dutch hospitals and associations for health professionals in oncology care were asked to circulate the questionnaire link to their employees or members (i.e. physicians and nurses). In addition, social media (Twitter and LinkedIn) were used to publicize the survey. The questionnaire was available online from April to June 2015. Respondents were excluded from analyses if they did not work as a physician or nurse (practitioner) in a hospital (N=45), or when they had not completed any of the questions in the second part of the questionnaire (N=8).

### **5.2.2 Questionnaire**

Participants' background characteristics and experiences with audio-recordings were covered in the first seven questions (see Table 1). The second part of the questionnaire was tailored to the respondents' stated experience. The closed questions in this part (see figure 1) concerned the influence of audio-recordings on the patient-provider interaction and perceived risks, based on experience or expectations. Health professionals may have acquired experience with consultation audio-recordings because the hospital facilitates recording, or because patients ask for permission to record the consultation. A distinction was made between these two situations in the questions because respondents who have experience with audio-recordings facilitated by the hospital may have had additional information that influenced their views. Also, their patients may not have felt the need to make the recording themselves as it was provided for them. The respondents without the experience of audio-recordings facilitated by the hospital were questioned about their experience with audio-recordings initiated by patients.



A 5-point Likert scale was used to categorize the respondents' experience and views (figure 1). After each question, the respondents were encouraged to elaborate on the answer given to clarify their views. At the end of the questionnaire there was room for additional comments.

### **5.2.3 Data analysis**

Descriptive statistics were used to identify the respondents' experiences and views. Linear regressions were conducted, with the health professional's age, gender, type of hospital (university/non-university), profession (physician/nurse), work experience in years, and experience with consultations being recorded (none/via the hospital/via patients) as predictor variables. STATA 13.0 was used to conduct these analyses.

The analysis of the clarifications to the closed questions aimed at obtaining insight into the nature of the respondent views. Two researchers started the open coding process (initial codes given to fragments of text), which was gradually replaced by axial coding (describing codes and integration in broader related concepts) performed by one researcher. Unclear quotes were discussed with the second researcher. Fragments explaining issues that may impede or facilitate the use of consultation audio recordings were coded. We then classified fragments that explained the perceived impact of using consultation audio recordings on the patient, the health professional and the patient-professional relationship. Since we did not find any new themes related to the research question in the last coded questionnaires, data saturation appeared to be reached. These analyses were conducted using MAXQDA 11.

## **5.3. Results**

### **5.3.1 Sample characteristics and experience**

The respondents consisted of 215 health professionals in oncology care: 123 physicians and 92 nurse (practitioners). A minority of the respondents had experience with consultation audio-recordings facilitated by their hospital (N=37, 17%). The others (N=178, 83%) were questioned about their experience with audio-recordings initiated by patients. Two-thirds of this group (N=116) had been confronted at least once by a patient who wanted to record the consultation, and the vast majority (N=96, 83%) had given permission for the recording (Table 1).

**Table 1** Respondents' characteristics and experience.

Background characteristics				All N=215	Physicians N=123	Nurses N=92
Age (5 missing)	mean (sd)			46.1 (9.8)	46.7 (9.6)	45.2 (10.0)
Work experience in years	mean (sd)			18.0 (10.0)	16.6 (9.5)	20.0 (10.3)
Gender	Male	N (%)		73 (34)	63 (51)	10 (11)
Type of hospital	University	N (%)		101 (47)	74 (60)	27 (29)
	Non-university			114 (53)	49 (40)	65 (71)
<b>Experience - facilitated by the hospital</b>						
My hospital facilitates audio-recordings (sometimes) and provides them to patients. (N=215)	Yes	N (%)		37 (17)	28 (23)	9 (10)
	No			178 (83)	95 (77)	83 (90)
<b>Experience - initiated by patients*</b>						
I have experience with patients who ask if they can make a recording. (N=178)	Yes	N (%)		116 (65)	77 (81)	39 (47)
	No			62 (35)	18 (19)	(53)
I give permission when a patient wants to make a recording. (N=116)	Yes	N (%)		96 (83)	60 (78)	36 (92)
	Sometimes			8 (7)	8 (10)	0
	No			12 (9)	9 (12)	3 (8)
I would give permission if a patient wanted to make a recording. (N=62)	Yes	N (%)		38 (65)	10 (59)	28 (68)
	Perhaps			16 (27)	5 (29)	11 (27)
	No			4 (7)	2 (12)	2 (5)

\*These questions were only posed to respondents who did **not** have experience with consultation audio-recordings via their hospital N=178.

### 5.3.2 Perceived risks and influence on the consultation process

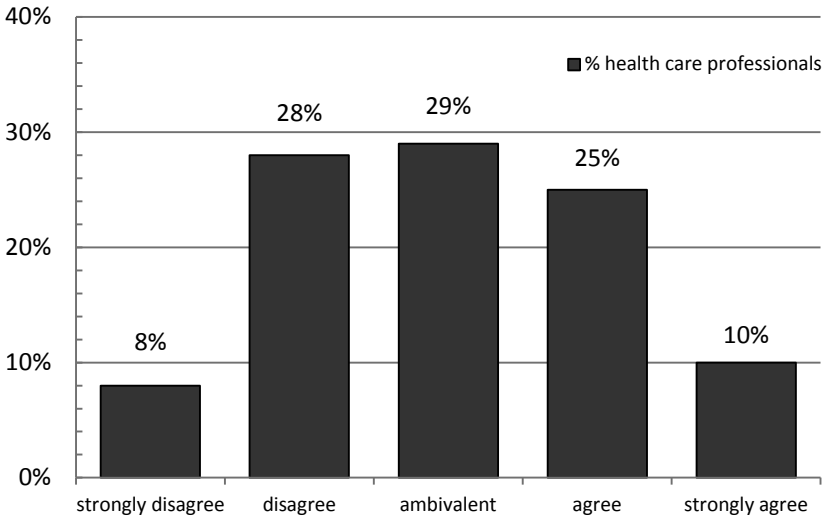
In figure 1 results of the inquired risk perception and experienced influence of consultation audio recordings on the consultation process are visualized. All respondents were asked to say whether they agreed with the statement 'I think there are risks related to the recording of consultations'. Their risk perception was divided, as 34% agreed (strongly) and 36% disagreed (strongly).

The 153 respondents who were familiar with the use of consultation audio-recordings (initiated either by the hospital or by the patient) were asked if they had found the recordings to have any influence on the consultation process. This question was answered by 141 participants, and a minority of 14% experienced the recording as (very) inconvenient, 52% said that it was not inconvenient (at all). In addition, 34% indicated that they communicated more carefully with the patient, knowing that the consultation was being recorded, 38% felt not influenced by the recording.

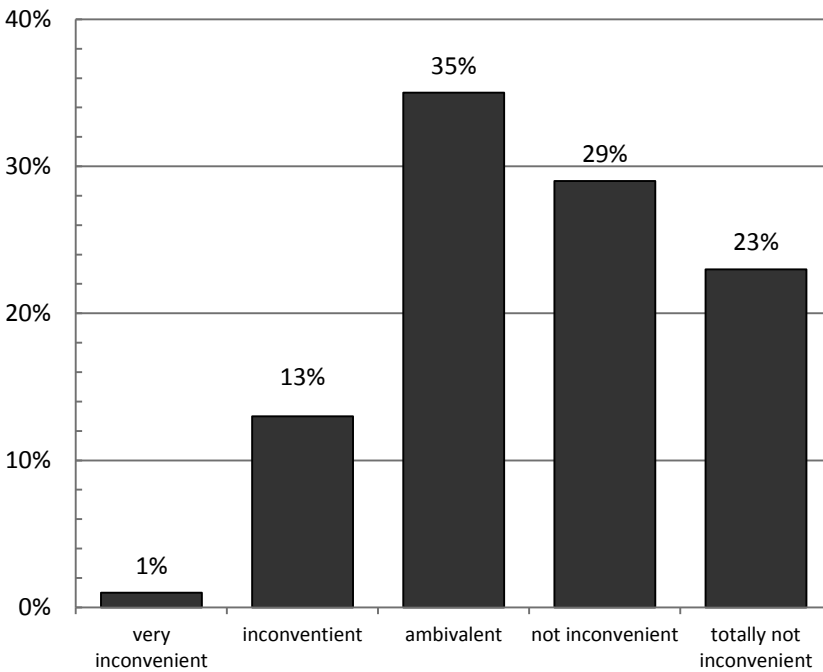
The analysis of the relations with, sociodemographics showed physicians tended to be more concerned about the risks than nurses ( $B = -.51$ ,  $p = 0.009$ ; 'physicians' mean 3.2, sd 1.2 vs 'nurses' mean 2.8, sd 1.0). A significantly greater proportion of male health professionals indicated that they experienced the recording as not inconvenient compared with female professionals, who were more ambivalent ( $B = 0.39$ ,  $p = 0.036$ ; 'male' mean 3.8, sd 1.1 vs 'female' mean 3.5, sd 1.0). Female health professionals were more likely to communicate more carefully when being recorded compared with male professionals ( $B = 0.42$ ,  $p = 0.037$ ; 'male' mean 2.7, sd 1.0 vs 'female' mean 3.0, sd 1.0); younger professionals were more likely to communicate more carefully than older professionals ( $B = -0.41$ ,  $p = 0.021$ ); and physicians were more likely to communicate more carefully than nurses ( $B = -.47$ ,  $p = 0.039$ ; 'physicians' mean 3.0, sd 1.1 vs 'nurses' mean 2.8, sd 0.9).

**Figure 1** Perceived risks and influence of the consultation audio recordings

**I think there are risks related to the recording of consultations (N=196)**

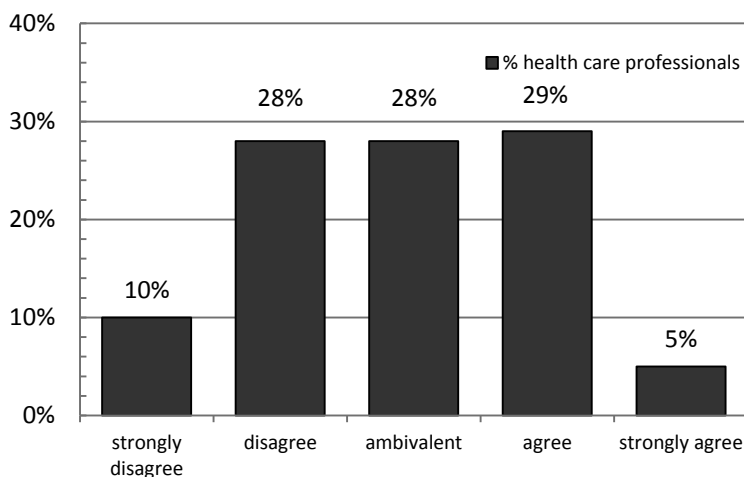


**I experience the recording of a consultation as... (N=141)**

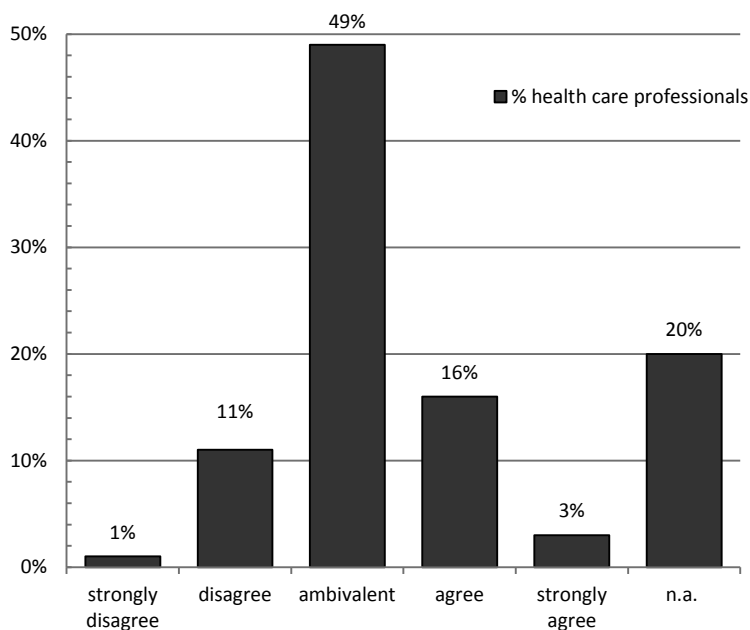


- Figure 1 continues -

**I communicate more carefully with the patient if I know that the consultation is being recorded (N=141)**



**In my experience, the communication in follow-up consultations improve when patients have the opportunity to listen back to a consultation audio-recording of the previous consultation (N=139)**



### 5.3.2 Perceived risks and influence on the consultation process

In figure 1 results of the inquired risk perception and experienced influence of consultation audio recordings on the consultation process are visualized. All respondents were asked to say whether they agreed with the statement 'I think there are risks related to the recording of consultations'. Their risk perception was divided, as 34% agreed (strongly) and 36% disagreed (strongly).

The 153 respondents who were familiar with the use of consultation audio-recordings (initiated either by the hospital or by the patient) were asked if they had found the recordings to have any influence on the consultation process. This question was answered by 141 participants, and a minority of 14% experienced the recording as (very) inconvenient, 52% said that it was not inconvenient (at all). In addition, 34% indicated that they communicated more carefully with the patient, knowing that the consultation was being recorded, 38% felt not influenced by the recording.

The analysis of the relations with, sociodemographics showed physicians tended to be more concerned about the risks than nurses ( $B = -.51$ ,  $p = 0.009$ ; 'physicians' mean 3.2, sd 1.2 vs 'nurses' mean 2.8, sd 1.0). A significantly greater proportion of male health professionals indicated that they experienced the recording as not inconvenient compared with female professionals, who were more ambivalent ( $B = 0.39$ ,  $p = 0.036$ ; 'male' mean 3.8, sd 1.1 vs 'female' mean 3.5, sd 1.0). Female health professionals were more likely to communicate more carefully when being recorded compared with male professionals ( $B = 0.42$ ,  $p = 0.037$ ; 'male' mean 2.7, sd 1.0 vs 'female' mean 3.0, sd 1.0); younger professionals were more likely to communicate more carefully than older professionals ( $B = -0.41$ ,  $p = 0.021$ ); and physicians were more likely to communicate more carefully than nurses ( $B = -.47$ ,  $p = 0.039$ ; 'physicians' mean 3.0, sd 1.1 vs 'nurses' mean 2.8, sd 0.9).

### 5.3.3 Prevailing views and perspectives

A total of 470 clarifying quotes were analysed to get an understanding of the professionals' views on consultation audio-recordings. Five themes were identified that may influence the use of consultation audio recordings at the initiative of patients;

#### i) Perception on effectiveness of the consultation audio recordings

There was no consensus about in the perceived effectiveness of the recordings. On the one hand respondents explained the perceived assets for patients in terms of (a)

increased understanding, (b) increased recall of information, and (c) the opportunity to share information with relatives. Also, the patient's 'right' to have a recording was frequently mentioned.

*Physician A: "The patient is better informed by listening back or letting others hear what has been discussed".*

*Nurse A: "I think it is the patient's right. It is well known that people don't remember everything you tell them or explain, so it should be possible to have something you can listen back to when you are at home."*

On the other hand, respondents expressed their scepticism about the benefits, and the perception that listening back to a recording is confusing for patients due to the lack of context and absence of non-verbal communication.

*Physician176: "I do not think it is valuable to record something, either for the understanding or for the fine details."*

*Nurse252: "Patients may stick too firmly to the recording and interpret it wrongly".*

## **ii) (Lack of) control over the recording**

Many antagonistic attitudes were related to the lack of control professionals felt to have over the recording and the related fear of misuse (e.g. through social media). In this context the privacy of the health professional was also mentioned.

*Physician138: "Unclear what will happen with this recording. Issues can get out of context or used in fragments."*

*Physician5: "In a strange way, it feels like it infringes my own privacy. You have no idea where your conversations end up".*

*Nurse121: "Also take the privacy of the health professional into account. That is not getting any attention at all."*

## **iii) Uncertainty about medico-legal status**

In relation to the aforementioned topic, uncertainty about the legal status of the audio-recordings was expressed several times.

*Physician97: "I think the recordings can be useful, but then we must have clear medicolegal regulations. This needs to be taking care of before starting to record consultations."*

*Physician145: "I would not want the literal things I said to be used against me in a legal dispute. If I know that I'm covered against that, I would have no objections against recording all conversations".*

#### iv) Perceived influence on the communication style of the professional

The quotes clarifying the perceived influence of audio-recordings on communication styles varied. On the one hand, quotes indicated that audio-recordings do not lead to a change in the communication style and even that they should not be a reason to change, i.e. it is wrong to change what you say.

*Nurse41: "It should not make any difference if you are being recorded. You have the obligation to inform patients adequately."*

On the other hand, respondents reported that they (would) choose their words more carefully. The reasons given for changing their communication style included the aforementioned fear of misuse, the fear of legal consequences, and feeling pressured.

*Physician277: "It may stop me expressing my opinion freely a little bit, also because of liability issues."*

*Physician207: "The doctor is less spontaneous and more constrained in their communication, the doctor will cover themselves, explaining more side effects than strictly necessary; defensive medicine, a suspicious atmosphere."*

Other, more positive explanations given concerned the perceived awareness that patients and relatives need to understand the recording in and of itself.

*Nurse229: "I'm more aware that patients listen back at home to what is being said. I try to be as clear as possible, but I'm not more careful the information I give is the same as when there is no recording."*

#### v) Trust

Respondents expressed their feeling of distrust that may inhibit the doctor-patient relationship.

*Physician143: it feels like distrust, being caught on your words.*

*Physician15: patients who want this are more wary and critical towards their health care professional"*

Related to trust, many respondents indicated that they do give permission to a patient, on the condition that the patient agrees to private use only.

*Physician96: "I do ask the patient not to circulate this information on social media. For personal use only."*

*Nurse230: "As long as there are concrete agreements being made about providing third parties with this information."*



## 5.4 Discussion

### 5.4.1 Summary of findings

In this explorative study, 215 health professionals in oncology care shared their experiences with consultation audio-recordings and their views on the use and implementation of audio-recordings. The number of reactions to the questionnaire and the detailed, sometimes strongly worded answers demonstrate that consultation audio-recordings are a topical issue. The majority of the respondents did have experience with consultation audio-recordings. Despite existing concerns, most respondents (would) cooperate with patient initiated recordings.

Respondents in favour of the audio-recordings seemed to embrace the evidence-based benefits for patients and mentioned the positive influences on their patients. Views that were antagonistic to audio-recordings included i) scepticism about the benefits and the believe that patients may be confused or misinterpret information when listening back, ii) the perceived lack of control once patients had a recording (risk of misuse), iii) the unclear legal status and iv) the influence on their communication style and v) the feeling of distrust that may inhibit the doctor-patient relationship. For a considerable number of respondents, these arguments were reason enough not to cooperate at all. The percentage of physicians opposed to the use of audio-recordings is comparable to a study in 1994 evaluating consultation audiotapes with summary letters [17]. The reported concerns match previous research involving studies where patients were provided with tapes on the initiative of the professionals [18, 22-24]. With the rise of popularity of social media from the time of those studies, the more prevalent expressed fear of misuse via social media found in the current study seems evident.

### 5.4.2 Practice implications and future research

Audio-recordings are expected to be used increasingly by patients [20]. Accepting this trend as a new way of using consultation audio-recordings seems feasible from the perspective of the participants in the current survey, but the existing concerns need to be tackled to increase transparency. Moreover, the high response number of 'ambivalent' (Figure 1) may indicate that there is a considerable group of respondents that has not yet formulated a clear opinion on certain issues related to the consultation audio-recordings, or they see both advantages and disadvantages. Future research may include in-depth interviews to learn more about the doubts and uncertainties professionals have with regard to the (impact of) recordings.

Drawing on the fundamental implementation components that Hack et al. proposed when *providing* consultation audio-recordings to patients [25], some of the existing concerns may be eliminated by a) providing information about the existing evidence-based benefits of listening back to consultation audio-recordings, and b) clarifying medico-legal regulations<sup>1</sup>. Future research should clarify if professionals feel less constrained when they are better informed about the potential benefits and legal status of the recording.

Discussion between professionals about the conditions under which permission for recording is given may increase transparency and reduce the feeling of inhibition. Increasing transparency may even take this approach a step further; convincing professionals to encourage patients to record the consultation. It is not likely that patients will initiate the recording in the first oncology consultation in particular, when patients are not yet familiar with this type of encounter and do not know what to expect.

To inform health professionals, further research should clarify the frequency and consequences of misuse and the influence on the patient-provider interaction in practice. Transparency about these topics may support patients to take the initiative to make a consultation audio-recording.

### 5.4.3 Limitations

Our method of recruitment limits the representative of the study by the absence of information about non-respondents and information on the diversity in institutions they worked in. Professionals who were willing to express their views in the current study may have stronger opinions compared with the population at large. In the present study only professionals in oncology care were asked to complete the questionnaire. Previous research shows that oncologists tend to be more in favour of consultation audio-recordings compared with surgeons and family doctors [18, 22]. Professionals may have different views and experiences in other settings, where less critical or complex information is shared. At last, we did not measure how much experience the professionals had with patient-recordings; the variable was either yes or no. Professionals with more experience may have different attitudes compared to those with less.

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<sup>1</sup> These regulations differ per country. In the Netherlands for example, it is permitted to (covertly) record a conversation, as long as you are one of the conversational partners. However, without permission of all conversational participants it is not allowed to make the recording publicly available.

#### **5.4.4 Conclusion**

Overall, Dutch health professionals in oncology care seem to support patient initiated consultation audio-recordings but many concerns exist and need to be tackled. While the majority cooperates when their patient asks to record the consultation, the concerns are for a considerable number of respondents reason enough not to cooperate.

#### **Acknowledgements**

We thank the respondents for completing the questionnaire. We are grateful to the Alpe d'HuZes program of the Dutch Cancer Society for their financial support.

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# 6

## Communication during haematological consultations; patients' preferences and professionals' performances

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*Published as:*

van Bruinessen IR, van der Hout LE, van Weel-Baumgarten EM, Gouw H, Zijlstra JM, van Dulmen S. Communication during haematological consultations; patients' preferences and professionals' performances. *Annals of Hematology*, 2016 June 95(7) 1177-1183.

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## Abstract

Many patients with haematological malignancies experience barriers in clinical communication. Reaching effective communication is of great importance as it has been linked to a range of improved patient outcomes such as satisfaction, compliance to treatment, perceived quality of life and physical and mental health. To get a better understanding how communication in haematological consultations can be improved, the current study focussed on patients' preferences and perceived performances regarding the communicative behaviour of their health care professional. Secondly, the mediation of an online communication tool for patients was analysed. Within a controlled pre- post-test design, 78 datasets of clinical consultations could be analysed. Patients considered both affective and instrumental communication aspects important. The affective communication behaviour of the health care professional met the patients' pre-visit preferences well. In the information exchange, more variability and discrepancies were found. Overall, the online intervention did not seem to influence the patients' perceived communication performance of their health care professional much. To further improve the communication during clinical consultations, health care professionals should inquire about patients' expectations, especially during the exchange of information and advices. At the same time, patients should be supported to express their preferences at the start of the consultation. The study was registered in the Netherlands Trial Register, number 3779.



## 6.1 Introduction

Communication is considered an essential part of high-quality patient care [1, 2]. In clinical communication, instrumental and affective components play an important role [3–5]. Instrumental communication relates to the necessary task-oriented information exchange, managing biomedical aspects and addressing patients' need to "know and understand". Affective communication relates to creating a therapeutic relationship, gaining patients' trust, managing psychosocial aspects and addressing patients' need to "feel known and understood".

Reaching good communication is of great importance as it has been linked to a range of improved patient outcomes such as satisfaction, compliance to treatment, perceived quality of life and physical health [6–10]. To establish effective communication, both the health care professional (HCP) and the patient need to participate actively [11]. However, the complex nature of medical interactions challenges both parties, which is even more evident in oncology care where burdensome issues need to be discussed [12]. HCPs have been trained and they are responsible for facilitating the process and content of the clinical communication. At the same time, patients are increasingly expected to be informed participants and to be able to make conscious decisions [13]. In practice, their conversational contributions appear to be limited [14–16] and patients continue to have unmet needs [17, 18]. These findings have resulted in an increased focus on supporting patients with communication [19, 20].

Patients with malignant lymphoma (Hodgkin and non-Hodgkin lymphoma) have indicated to experience barriers in communicating effectively [21, 22]. They relate these difficulties to their own attributes (e.g. emotions, communication skills), the HCPs' attributes (e.g. attitude, communication skills) and external factors (e.g. time pressure) [21]. The often long periods of uncertainty around diagnosis and the emotional position of the patient pose a challenge to communicate effectively in the initial phase of the disease. After primary treatment, communication remains challenging when new issues arise, such as fatigue, depression, anxiety for second primary cancers or the fear to never reach a complete remission [23–25]. According to the biopsychosocial model [5], patients need room to communicate about these disease-specific issues and they also look for emotional support, i.e. they need to be heard and taken seriously by an attentively listening doctor. How outpatients cope between hospital visits depends partly on the information and support they receive

during the visits. Therefore, it is important for them to get the most out of these visits [26].

Addressing patients' individual preferences and needs is crucial in establishing trust, gathering information and assisting patients in making decisions [1]. To get a better understanding how patients and professionals in haematological care can be supported in reaching effective communication, the current study focussed on patients' communication preferences and perceived performances. We inquired patients' pre-visit preferences regarding to their forthcoming visit. Post-visit, the affective and instrumental communicative behaviour of the HCP through patient's eyes was assessed.

Additionally, we evaluated to what extent an online communication intervention for patients mediated these perceptions. This intervention aims to support patients with their communicative contribution [27]. Increased awareness of the importance of communication and an increased knowledge level about communication strategies may positively influence their perceptions as a "side effect" of the intervention. However, it can also be hypothesized that the intervention raises expectations and causes a more critical attitude towards the doctor [28–30].

## **6.2 Design and methods**

This study is part of a larger study evaluating the effects of the online tool for patients aiming to support them in clinical communication (PatientTIME) [27, 31]. Patients were randomized in two intervention groups (getting access to the online tool before their forthcoming visit) and a control group (getting access after participation).

### **6.2.1 Setting and population**

Patients could express their interest in participation via online registration between March 2013 and May 2015. Patients were eligible for participation when diagnosed with a malignant lymphoma, aged 18 years or older, had at least one (follow-up) consultation with their HCP within a year, had a good understanding of the Dutch language and followed treatment or follow-up in a Dutch hospital.

We have focussed mainly on patients with malignant lymphoma while these patients are on long-lasting outpatient treatment. The contacts with their treating physician are with variable intervals during a long period.

### **6.2.2 The intervention**

PatientTIME aims to empower patients by supporting them in how to gain more control over the communication. The central information of the intervention consists of short video fragments (47–180 s) showing patients modelling different communication strategies during simulations of clinical consultations (e.g. utter the need for support, deal with emotions, ask questions). The fragments are based on communication barriers identified by the targeted population in a previous study [21].

### **6.2.3 Design and measures**

In a controlled pre-post-test study, we measured to what extent patients' pre-visit communication needs were fulfilled during the clinical consultation. This concept was defined as the degree to which the HCP's communication performance meets the patient's preferences [32]. For the current study, a total of 15 of the 19 items of the original validated QUOTE-com questionnaire were used [33–35] (Quality of Communication Through the patient's Eyes). These items can be divided into an instrumental and affective category. The patients reported per item how important the communication aspects were for their forthcoming visit and afterwards whether these needs were met by their HCP, on a four-point Likert scale (Table 2).

### **6.2.4 Statistical analysis**

Descriptive statistics were used to characterize the sample. Differences between groups were analysed using *t* tests and chi-square tests, where appropriate. Four subscales of the QUOTE were created: a (1) pre-visit instrumental scale, (2) pre-visit affective scale, (3) post-visit instrumental scale and (4) post-visit affective scale. The internal consistency of the four created sub-scales was high (Table 1). Linear regressions were conducted to analyse differences in perceived performance scores between the control and intervention group per item, adjusting for preferences score.

Initially, we also adjusted for time elapsed since diagnosis, as we expected this to influence the outcome. However, only in 4 of the 15 items the influence was significant, with a very small effect ( $C \leq 0.00$ ). Therefore, this variable was excluded from the final analysis. We repeated the analysis with ordered logistic regressions. This led to the same conclusions and therefore only the regressions were presented.

STATA 13.0 facilitated the analyses. Statistical significance was tested two-tailed at 0.05.

**Table 1** Background characteristics and preference and performance scores

Participants		Control N=28	Intervention N=50
Age (at registration)	mean years (sd)	56.7 (2.2)	55.6 (1.7)
Gender	male	11 (39%)	17 (34%)
Education	Low	2 (7%)	0
	Medium	6 (21%)	11 (22%)
	High	20 (71%)	39 (78%)
Member of a patient organisation	Yes	14 (50%)	36 (72%)
	No	14 (50%)	14 (28%)
Internet use	daily	26 (93%)	47 (94%)
	weekly	2 (7%)	3 (6%)
	monthly	0	0
Disease related information			
Diagnosis	Hodgkin lymphoma	3 (10%)	13 (26%)
	Non-Hodgkin lymphoma	24 (86%)	34 (68%)
	other	1 (4%)	3 (6%)
Time elapsed since diagnosis*	mean years (sd)	3.5 (0.7)	8,11 (1.5)
	< 1 year	9 (32%)	10 (20%)
	> 1 year	19 (68%)	39 (80%)
Treated	Yes	24 (86%)	47 (94%)
	No	4 (14%)	3 (6%)
Current status	awaiting research results or treatment (plan)	4 (14%)	5 (10%)
	currently getting treatment	6 (21%)	9 (18%)
	wait-and-see	9 (32%)	14 (28%)
	remission	9 (32%)	22 (44%)
	palliative care	0	0

- Table 1 continues -

- table1 continued -

Participants		Control N=28	Intervention N=50
<b>Details medical consultation</b>			
Consulted professional	physician	26 (93%)	50 (100%)
	nurse	2 (7%)	0
Familiar with professional	yes	28 (100%)	46 (92%)
	no	0	4 (8%)
With a companion	Yes	18 (64%)	27 (54%)
	No	10 (36%)	23 (46%)
<b>Mean preference scores</b>			
<b>Pre-visit preference score (range 1-4)</b>	instrumental scale ( $\alpha = 0.82$ )	3.37 (.38)	3.19 (.53)
	affective scale ( $\alpha = 0.78$ )	3.25 (.41)	3.36 (.38)
<b>Mean performance scores</b>			
<b>Perceived performance score (range 1-4)</b>	instrumental scale ( $\alpha = 0.80$ )	2.94 (0.62)	2.68 (0.85)
	affective scale ( $\alpha = 0.90$ )	3.72 (0.49)	3.57 (0.60)

\* one missing

## 6.3 Results

### 6.3.1 Participant flow

A total of 146 patients registered online of which total 97 were randomized in control or intervention group after providing informed consent. Registered patients who were not randomized did not meet the inclusion criteria ( $N=4$ ) or they did not return their informed consent form ( $N = 45$ ). This group did not differ from the randomized patients regarding age, gender, ethnicity, internet use and stage of the disease. However, the randomized patients were highly educated, more often member of a patient organization, the time between diagnosed and registration for participation was longer and they had started treatment more often. Of the randomized participants, 19 participants did not complete their post-visit questionnaire ( $N = 9$ ) or signed off before the start of the research ( $N=10$ ), leaving 78 datasets to be analysed.

### 6.3.2 Baseline data

The baseline characteristics of the intervention group ( $N=50$ ) and the control group ( $N = 28$ ) were similar, except for the elapsed time since diagnosis, which was significantly longer for the intervention group ( $p = 0.01$ ). The majority of all participants were highly educated and a quarter of the participants were diagnosed in the last year. Most patients (97 %) had visited a physician.

### 6.3.3 Preferred and perceived communication performance

The mean preferences and perceived performances scores are presented in Table 1. Results on item level are presented in Table 2. Overall, the perceived performance score on the instrumental scale is lower compared to the perceived performance score on the affective scale for both groups.

On the instrumental scale, six (of eight) items were considered (very) important by 90–99 % of the patients. Patients consider advice on what they can do as most important instrumental preference. The two items “the HCP should examine me” and “the HCP should diagnose what’s wrong” were less frequently indicated as (very) important (respectively 72 and 74 %). In the eyes of the patients, five needs were fulfilled in more than 70 % of the cases. The items “the HCP should discuss different treatment options” and “the HCP should give information about possible side effects” scored lowest on perceived performance. While patients considered these items as important needs (respectively 92 and 94 %), they were not often perceived as having been met (respectively 39 and 40 %).

On the affective scale, six (of seven) items were considered (very) important for their forthcoming visit (88–99 %) by most patients. The item “the HCP should be empathetic with me” was considered important (65 %) less often compared to items as “the HCP should be frank to me” (99 %) and “the HCP should take enough time for me” (97 %). Overall, the perceived performance met the pre-visit affective preferences well (84–96 %) and lesser discrepancies were visible compared to the instrumental scale.

**Table 2** Perceived performance of the health care professional when pre-visit indicated as (very) important

THE INSTRUMENTAL SCALE		preferred by: N (%)	N* (%) that perceived that the pre-visit need was met		
The healthcare professional...		Total	Control	Intervention	
examined me	56 (72%)	43 (77%)	18 (75%)	25 (78%)	
diagnosed what's wrong	58 (74%)	41 (71%)	17 (74%)	24 (69%)	
explained well what's wrong	73 (94%)	62 (85%)	25 (96%)	37 (79%)	
gave advice on what to do	77 (99%)	55 (71%)	21 (75%)	34 (69%)	
helped me with my problem	70 (90%)	43 (61%)	15 (58%)	28 (64%)	
informed well on the treatment	75 (96%)	56 (75%)	22 (79%)	34 (72%)	
discussed different treatment options with me	72 (92%)	28 (39%)	12 (46%)	16 (35%)	
gave information on possible side effects	73 (94%)	29 (40%)	11 (41%)	18 (39%)	
THE AFFECTIVE SCALE		preferred by: N (%)	N* (%) that perceived that the pre-visit need was met		
The healthcare professional...		Total	Control	Intervention	
was friendly	69 (88%)	66 (96%)	24 (96%)	42 (95%)	
took my problem seriously	77 (99%)	67 (87%)	25 (93%)	42 (84%)	
listened well to me	77 (99%)	69 (90%)	25 (93%)	44 (88%)	
was frank to me	77 (99%)	73 (96%)	26 (96%)	47 (96%)	
took enough time for me	76 (97%)	71 (93%)	26 (96%)	45 (92%)	
was empathetic to me	51 (65%)	43 (84%)	16 (89%)	27 (82%)	
gave me enough attention	75 (96%)	69 (92%)	26 (96%)	43 (90%)	

\*Sample size varies due to pre-visit preference scores; only post-visit experience scores of patients who indicated these items pre-visit as important (scores 3 or 4) are mentioned.

### 6.3.4 Intervention effects

Controlled for preference scores, there were no significant differences between the intervention and control group on perceived performance scales on item level. The similarities and discrepancies between the perceived performance are presented in the right columns of Table 2.

On all 15 items, the intervention group coefficient was negative (ranging from  $-0.06$  to  $-0.43$ ), indicating that they perceived the communicative performance of their HCP lower than the control group.

## 6.4 Discussion

In the present study, we investigated preferences and perceived performances regarding the communicative behaviour of their HCP, through the eyes of patients with malignant lymphoma. In agreement with comparable studies in general practice and oncology care, participants in the current study consider both affective and instrumental communication aspects important [32, 36–38]. Patients were predominantly satisfied with the affective communication style of their HCP, which is a positive result. They considered their HCP as friendly, frank and a good listener who took enough time.

There were more discrepancies between needs and perceived performance in instrumental, task-oriented domain. Three items in particular stood out. Patients considered information about treatment options and side effects as important, but in practice these two needs were often perceived as unmet. These topics may not have been relevant for the concerning consultation from a clinical point of view, but the patients did prefer to talk about them. In this respect, upfront agenda setting may help to establish consensus about the joint focus of the consultation [39]. Third, patients think it is highly important to get advice about what they can do. The need for clear information has been pointed out in other studies [22, 40], but the need to know how one can act seems a step further. The increasing emphasis on patient autonomy, patient participation and shared decision-making may explain this development [41, 42]. Considering the relatively high average time elapsed since diagnosed, this proactive attitude may be associated with the experience these patients had gained. Experience can support patients to act more proficient and empowered to ask certain questions [21].

In the second part of this study, we assessed to what extent the online communication tool “PatientTIME” influences patients’ perceived performances regarding their HCP’s communicative behaviour. The data indicated no significant



differences between the intervention and control group. This suggests that the intervention does not influence the perceived performances but hopefully the patients' actual behaviour or confidence in their own communication performance. A lack of power may be a reason for the absence of significant results between the control and intervention group, because it is remarkable that the findings on item level demonstrate a negative trend on all 15 items. This indicates that the intervention group may have been more critical about their HCP's performance as a result of the intervention. Watching PatientTIME's video clips of best communication practices may have raised expectations, increased tensions or led to a more critical attitude towards the HCP, like suggested in other studies evaluating patient-targeted interventions [28, 29, 43].

The current study had the following limitations: first, the inclusion of participants was based on voluntary registrations. This may have led to a group of participants with a relatively increased interest in (improving) the quality of clinical communication. Second, the majority of the participants were highly educated and the time elapsed since diagnosis was quite long. This indicates that they were relatively experienced in the health care system, a known phenomenon in research that involves eHealth interventions (the inverse information law; "access to information is often most difficult for those who need it most") [44]. This challenges the generalizability of our results to lower educated and less experienced patients.

Third, the QUOTE-com questionnaire has originally been developed and validated for primary care. In the current study, four items of the questionnaire were excluded because these were not applicable for patients diagnosed with cancer. Adapted versions of the scale have been frequently used in secondary care [32, 45], but alterations may influence the validity. Moreover, the participants in the current study may have multiple hospital visits planned for different purposes and therefore a "not applicable" answer option might have been of added value.

Fourth, it is likely that directly after having watched PatientTIME's video clips, the preferences and expectations of the intervention group about the upcoming conversation changed. Because we offered no post-website questionnaire, we do not know to what extent the intervention influenced the pre-visit preferences. It would be interesting to assess whether the intervention changes the expectations, which may also support the interpretation of data gathered post-visit.

At last, the setting and recruitment method provided us with information gathered via the patient only and little detailed information about the HCP (like

years of experience) which could have enriched the interpretation of the results.

In conclusion, patients considered both affective and instrumental communication aspects important during haematological consultations. On the affective scale, the perceived performance of their HCP met their pre-visit preferences well. On the instrumental scale, patients' expectations were fulfilled less. Overall, the online pre-visit communication tool for patients "PatientTIME" did not seem to influence the patients' perceived communication performance of their own HCP much.

To further improve communication during clinical consultations, HCPs should inquire patients' communication preferences and expectations at the start of the consultation, especially on the instrumental domain. Improving this skill can be taught in communication skills training, which have proven to be an effective approach [46]. At the same time, patients should be supported to clarify their preferences.

### **Acknowledgments**

The authors would like to thank all participants for their kind co-operation and the Alpe d'HuZes programme of the Dutch Cancer Society for funding this study.

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# 7

## An integrated process and outcome evaluation of a Web-based communication tool for patients with malignant lymphoma: randomized controlled trial

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### *Published as*

van Bruinessen IR, van Weel-Baumgarten EM, Gouw H, Zijlstra JM, van Dulmen S An integrated process and outcome evaluation of a Web-based communication tool for patients with malignant lymphoma: randomized controlled trial. *Journal of Medical Internet Research* 2016;18(7):e206

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## Abstract

**Background:** The complex nature of the medical dialogue and the often emotional context in cancer care present challenges to health care professionals (HCPs) and patients. Patients are increasingly expected to be informed participants and to be able to make conscious decisions, which they often find very difficult. In an attempt to support patients with malignant lymphoma in clinical communication, we developed a stand-alone, Web-based intervention called “PatientTIME.” The development of PatientTIME was based on a participatory intervention mapping framework. Its primary aim is to boost patients’ self-efficacy in patient-professional communication (ie, their confidence when interacting with their HCP). Patients can use this intervention before their hospital visit to prepare for their clinical consultation. PatientTIME is fully automated and use is patient-initiated.

**Objective:** The aim of this study was to evaluate if and in what way patients benefit from PatientTIME and if it enhances their confidence in clinical communication.

**Methods:** The intervention was evaluated in a closed randomized controlled trial with continuous recruitment (using online and offline methods to reach potential participants) and data collection. In accordance with the Medical Research Council guidance, we started with a process evaluation. Subsequently, an outcome evaluation was performed focusing on the patients’ perceived confidence in communication with their HCP, measured with the validated PEPPi questionnaire at baseline and at 3 months after participation. Process and outcome data were obtained through Web-based questionnaires, log files (automatically generated files mapping the interactions between program and users), and a logbook (comprising a record of actions and interactions kept by the researchers). Participants were not blinded. A total of 146 patients registered online, of whom 97 gave their informed consent and were assigned at random to the control group (N=34) or 1 of the 2 intervention groups (N=63). Ultimately 87/97 (90%) of these patients actually participated in the study, producing 87 datasets for analysis.

**Results:** More than half of the intervention group patients reported that the intervention helped them prepare for a clinical consultation; it created awareness about the importance of communication and reinforced their existing communication skills. In the postvisit test, the control group showed a small, nonsignificant improvement in perceived communication efficacy. The intervention group showed a significant improvement in perceived efficacy. However, the interaction effect was not significant, indicating that the improvement solely as a



result of the intervention may not be significant.

**Conclusions:** A considerable number of patients reported that PatientTIME did provide support. We found a trend indicating that in the long run, patients with access to PatientTIME scored better on the perceived efficacy scale than patients without access. However, at this stage we cannot conclude that PatientTIME improves patients' confidence when interacting with HCPs.

## 7.1 Introduction

The interaction between the health care professional (HCP) and the patient is the fundamental vehicle for exchanging information. For the HCP, effective communication is necessary to manage and resolve biomedical and psychosocial problems, which are key issues in cancer care. For the patients it is important to "know and understand," and the communication serves a purpose in their need to "feel known and understood" [1].

It is important to have effective communication in order to deliver good care. Indirectly, effective communication has been linked to a range of improved patient outcomes such as satisfaction, treatment compliance, perceived quality of life, and physical health [2-6]. However, the complex nature of the medical dialogue and the often emotional context in cancer care are a challenge for HCPs and patients, and the quality of communication often remains suboptimal [7]. Although the HCPs are responsible for the communication process, the increased focus on patient empowerment and shared decision making has broadened the role of patients [8-10]. Patients are increasingly expected to be informed participants and to be able to make conscious decisions [11].

Research shows that such patient participation pays off: if patients participate actively, physicians provide significantly more information overall and respond better to questions [12]. Patients who reach their preferred level of participation experience less anxiety and are more satisfied with the clinical consultation [13]. However, most cancer patients do not achieve their desired level of participation [13,14]. Patients' communicative contribution appears to be limited [15,16] and patients report unmet communication needs [7,17]. Research has highlighted the importance of not only training the HCPs in communication skills, but also providing cancer patients with support in communication [18-20].

So far, cancer communication studies in clinical settings focus mostly on specific types of cancer, especially breast, prostate, and colorectal cancer [21]. Disease-specific communication instruments are lacking for patients with malignant

lymphoma. Via the Dutch patient association Hematon (for leukemia, malignant lymphoma, and stem cell transplantation), these patients have indicated that they often lack the skills needed to be more in control, participate more, and play a more active role during clinical consultations. Research confirms their need for support [22,23]. In an attempt to support patients with malignant lymphoma in communicating with their health professionals, we collaborated with these patients to develop the Web-based intervention “PatientTIME” [24]. Patients can use this stand-alone intervention before their hospital visit to prepare for clinical consultations (see Intervention). The primary aim of the intervention is to positively influence patients’ self-efficacy in patient-professional communication [25,26], that is, their confidence that they can interact with their HCP. Self-efficacy is an important predictor of actual communication behavior [21]. The effectiveness of PatientTIME was tested in a randomized controlled trial (RCT) with self-efficacy as the primary outcome measure.

Randomized controlled trials are considered to be the most rigorous way of evaluating effectiveness in the medical context. Traditionally, the main focus is on reporting prespecified outcomes. This evaluation method is predominantly applied in interventions with one active variable, for example, the effect of a drug on survival [27]. In interventions like PatientTIME, different active ingredients (Table 1) are combined and evaluated simultaneously. Oakley et al [28] argue that when evaluating such a “complex” intervention, incorporating a process evaluation would support and improve the interpretation of outcomes. Process evaluations look into the nature of the intervention, how it is delivered, and what actually happens during the intervention [29,30]. It can improve the validity and interpretation of outcomes, help refine the intervention, and provide necessary information for replication [27,30]. Despite the rise of complex interventions, few studies combine process *and* outcome evaluations.

In this study, knowledge about the process characteristics is expected to help in improving the PatientTIME intervention: it may show how to reach different patient groups and it can support the right interpretation of outcomes. Moreover, the process evaluation provides the context in which the data for the outcome evaluation are gathered. The main question to be answered by the outcome evaluation is “Does the intervention increase participants’ confidence in interacting with their HCP?”

The ultimate goal is to implement PatientTIME as a publicly available, stand-alone intervention, that is, without the research context and without the involvement

of professionals. In addition to giving insight into the effectiveness, the results of the study can help us optimize PatientTIME as a stand-alone intervention.

**Table 1** The intended use of the individual intervention components.

Intervention component	Intended use
Video library	Before a clinical consultation, a subset is selected from the 58 video fragments available for use in the video library. The selection is tailored to the user's preferences and needs at that time and stored in the user's personal video library. When the intervention is used again, new video fragments are added to the library along with the previously viewed videos (which are still available for viewing). Per consultation, video clips regarding a maximum of 3 communication themes are provided (6 clips in total). When using the intervention for the first time, a maximum of 4 introductory clips are added to the theme clips.
Question prompt	A prompt was integrated to encourage patients to set goals and prepare questions before the consultation. Patients can also formulate questions or remarks while watching the video fragments. The question prompt sheet can be printed or emailed to the patient's address.
Listening back to the consultation	A consultation audio recording can be uploaded, attached to the consultation date in the agenda, and replayed at any time.

## 7.2 Methods

### 7.2.1 Procedure and Ethical Approval

In accordance with the Medical Research Council (MRC) guidance, we started with a process evaluation focusing on the reach of the intervention and the extent to which it was used as intended [31]. Subsequently, the outcome evaluation was performed, focusing on the patients' perceived confidence when interacting with their HCP. The research ethics committee of the Radboud University Nijmegen Medical Centre evaluated the RCT protocol and concluded that the study did not fall within the remit of the Dutch Medical Research Involving Human Subjects Act (WMO). The study is registered in the Netherlands National Trial Register (trial registration number NTR3779). Written informed consent forms were used.

### 7.2.2 Intervention

The Web-based PatientTIME intervention aims to support patients in gaining more control over the communication with their HCP. The intervention development was guided by the intervention mapping framework applied in close collaboration with patients [24] and makes use of different theory-based methods: modeling, tailoring information, previsit goal setting, and listening to visit recordings. The central source of information in the intervention consists of 58 short video fragments (47-180 seconds) showing simulated patients demonstrating different communication skills during medical encounters (eg, stating the need for support, dealing with emotions, or asking questions; Figure 1) [32]. The fragments are based on communication barriers identified by the targeted population in a previous study [22]. A question prompt sheet (QPS) and an option to replay an audio recording of the user's hospital visit were also included in the intervention. The functionality and intended use of these individual components are described in Table 1. The collaborative partners (2 hospitals, the patient association, the funding organizations, and a research institution) were listed on an information page.

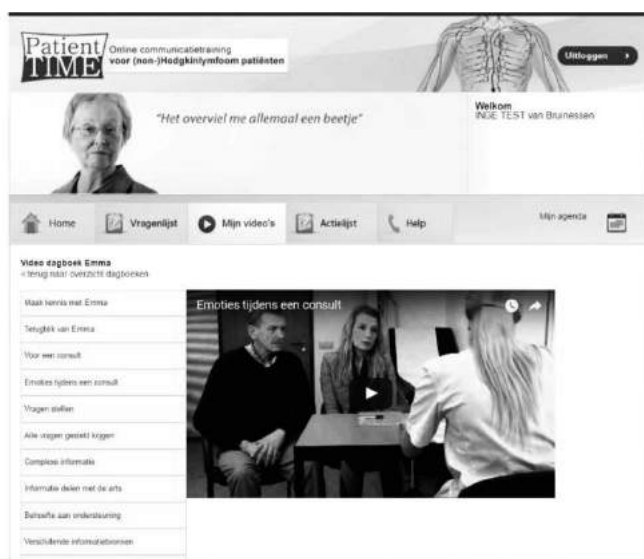


Figure 1 Screenshot of the PatientTIME intervention

### 7.2.3 Recruitment

PatientTIME is a stand-alone intervention; that is, patients can register and use the intervention without referral or the involvement of a professional. Several online and offline actions were organized to create awareness of the availability of PatientTIME: (1) spreading leaflets at hospital waiting rooms, (2) giving short presentations during patient information meetings arranged by Hematon and at hospitals, (3) short news flashes in Hematon's digital newsletter and magazine, (4) distributing our own project newsletters, and (5) using social media (Twitter, forums). Additional actions were initiated during the inclusion period: (6) we sent information packages and leaflets to hematologists asking them to distribute the information among their patients, and (7) we sent short news flashes about the study to local newspapers. Patients could express their interest in participating via registration on the PatientTIME website [21] between March 2013 and May 2015. After registration, the study's inclusion criteria were verified. Patients were eligible for participation if they were aged 18 years or older, had been diagnosed with malignant lymphoma, had at least one (follow-up) consultation with their HCP per year, had a good understanding of the Dutch language, were receiving treatment or follow-up care in a Dutch hospital, and had access to a computer with an Internet connection.

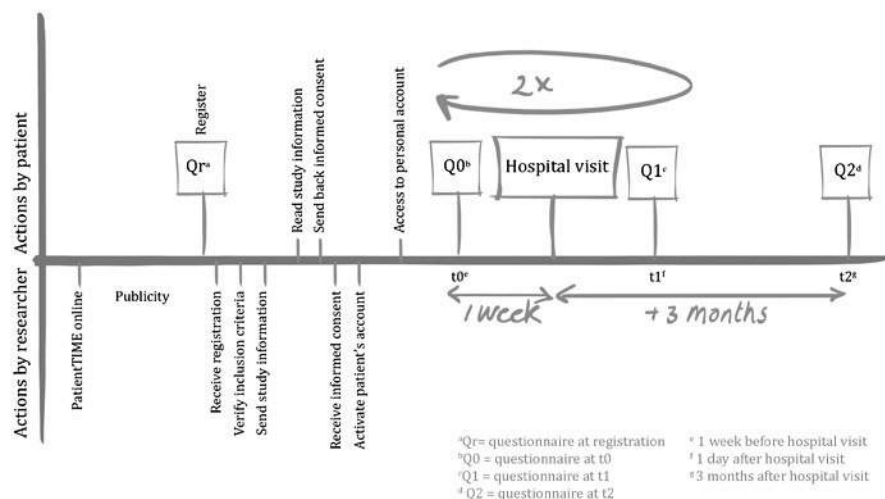
If the inclusion criteria were met, patients received a consent form with additional information by post. As soon as they had returned the informed consent form, their account was activated and an email was automatically sent to the patient with log-in details. If no consent form was returned, the patient was reminded by email after 2 weeks and by phone 1 week after that.

### 7.2.4 Design

The intervention was implemented in the form of a 3-armed RCT with continuous recruitment and data collection. The computer assigned participants randomly to 1 of 3 groups: (1) a control group, (2) an intervention group, and (3) an intervention audio group. Software that enabled blocked randomization (block size 3) was used to balance the groups.

The 2 intervention groups differed in one component: having or not having the opportunity to listen afterward to the audio recording of their clinical consultation. For the purpose of this outcome evaluation, the 2 intervention groups were evaluated as 1 group and compared with the control group. We made this decision for practical reasons. Patients who had the opportunity to listen afterward to their consultation generally did this after completing the postvisit questionnaire (Figure

2). Therefore, the experience of replaying and listening to the consultation could not have influenced their answers. Moreover, some patients in the intervention group where we did not actively encourage them to record their consultations (group 2) still made recordings on their own initiative.



**Figure 2** Timeline randomized controlled trial steps

All participants were given access to a personal secure Web account with questionnaires and an integrated digital agenda. The agenda had an automatic reminder system. This system led them through the study with personalized messages and questionnaires before and after clinical consultations (Figure 2). The date of the participant's forthcoming hospital visit determined the start of his or her participation. One week before this visit, participants received an automatic email reminder with the request to complete the previsit questionnaire on their Web account. After having completed the previsit questionnaire, the control group received no further information. The 2 intervention groups were given access to the intervention content (Figure 3). The selection of video fragments taken from the video library was based on the participant's self-reported previsit communication preferences and needs. The intervention audio group participants were also instructed—if permitted by their HCP—to record their consultations, upload the audio recordings, and listen afterward to them. The recordings were also available to the

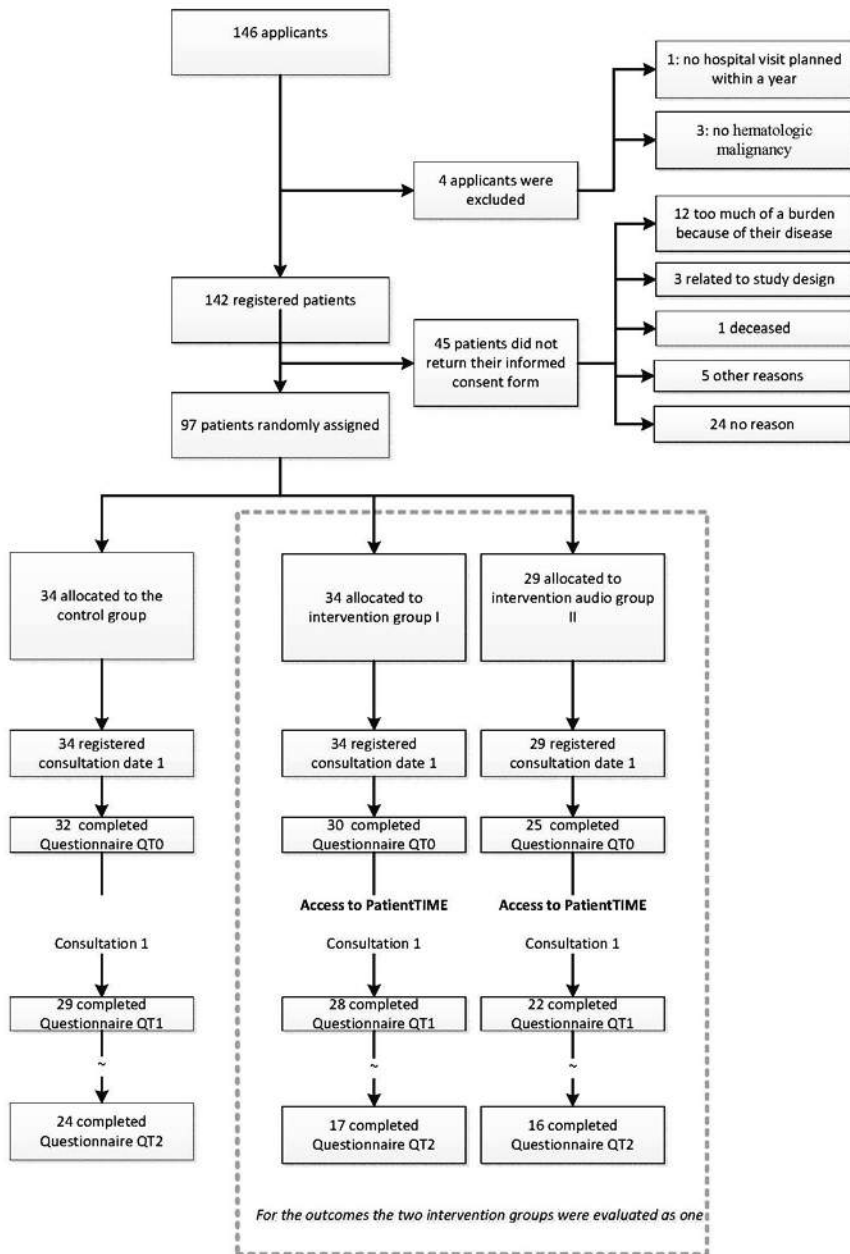


Figure 3 Flowchart.

researchers for analyses. We provided these participants with a small audio-recording device and extra information about consultation audio recordings.

The day after the consultation, patients received an automatic reminder with a link to the postvisit questionnaire. If a second and third consultation was planned within the participation year, the cycle was repeated with less comprehensive questionnaires. If necessary, a maximum of 2 reminders were sent by the researcher reminding the participant to complete the questionnaires or register a consultation date. The control group had access to the educational content of the intervention after participation.

There was no downtime during the evaluation period. PatientTIME's content and functionality were frozen for the duration of the trial. Necessary bug fixes were made relating to questionnaires that were not always directly available after the clinical consultation.

Participants were not blinded as they could see whether they had access to the content of PatientTIME or not. As self-confidence in communication was the primary outcome measure, the power calculation was based on the primary outcome measure of the RCT, the PEPPI (Perceived Efficacy in Patient-Physician Interactions) questionnaire (see Data Collection and Measures) [26]. We expected the intervention to result in a decrease of 5 points on the sum score (reflecting higher confidence), which corresponds to an effect size of 0.70. To detect this difference with a power of .80 and alpha of .05, we needed 50 patients in the intervention group and 50 patients in the control group.

#### **7.2.5 Data Collection and Measures**

The process and outcome data were measured through (1) Web-based questionnaires (Qr, Q0, Q1, and Q2; see Figure 2), (2) log files, that is, automatically generated files mapping the interactions between the program and its users, and (3) a logbook, comprising a record of actions and interactions that was kept by the researchers.

According to the MRC guidance, the selection of dimensions that are evaluated should be adjusted to the intervention under study. A total of 7 process dimensions were selected that may influence outcome measures in this study (Table 2)



**Table 2** Dimensions of the PatientTIME process evaluation.

Dimensions	Purpose	Research questions (data source)
Delivery		
Uptake	Insight into the procedures used to reach users, and information on who was reached	Were the publicity actions conducted as planned? (Logbook) Who showed interest in participating? (Questionnaire Qr) What were the reasons for not participating? (Logbook)
“Dose” delivered	Insight into the exposure to the intervention	To whom was the intervention delivered, and how does this compare to the population of interested patients? (Questionnaire Qr)
Participation rate	Insight into the characteristics of participants <sup>a</sup> and their reasons for participating	Who participated in the evaluation, compared with the total group who were invited to participate in the intervention? (Questionnaire Qr, Q0)
Fidelity	Insight into the extent to which the intervention was provided as planned	Which adaptations made to the intervention for the benefit of the effect evaluation may have influenced use and outcomes? (Logbook) What was the time between registration and the consultation date? (Questionnaire Qr) To what extent were reminders necessary for the benefit of the effect evaluation? (Logbook)
User-program interaction		
Dose received (attrition)	Insight into the actual exposure to the intervention and the use of its different components	How many video fragments were watched per patient? (Log files) How many patients used the question prompt sheet? (Log files) How many patients audio-recorded their consultation? (Log files)
Usability	Insight into the usability of the intervention	How was the satisfaction with the intervention rated? (Questionnaire Q1) <sup>b</sup>
Contextual factors		
Patient’s context	Insight into the contextual factors at the micro level	What influence does the patients’ context have and how could the context have influenced the outcome evaluation? (Logbook)

<sup>a</sup> A patient was defined as a “participant” if he or she registered the first consultation date and completed the previsit questionnaire Q0.

<sup>b</sup> The usability was evaluated with the System Usability Scale, a 10-item questionnaire that gives an overview of satisfaction with the program, resulting in a sum score (range 0-100) [33]. Usability tests had already been conducted with patients on a small scale during the development phase. However, as usability is strongly associated with use, attrition, and dropout, we decided to measure it on a larger scale as well.

In addition to the dimensions taken from the MRC guidance, the intervention group was asked if and in what way the intervention had helped them. All “evaluative” responses (answers to the question) were coded as “positive” or “negative.” To prevent subjective interpretation of the data, 2 researchers coded all fragments. The interrater reliability was good (81% agreement). Disagreements were discussed to come to an agreement.

For the primary outcome measure, participants were asked to complete the validated, 10-item PEPPI questionnaire twice: at t0 and t2. The PEPPI questions all begin with “How confident are you in your ability to...” and assess a patient’s confidence in their ability to communicate with their HCP on a 5-point Likert scale (1 = very confident to 5 = not confident at all) [26,34]. Item scores were summed (giving a range of 10-50), whereby lower scores reflect higher self-efficacy. The PEPPI questions used at t1 were reformulated so that they could also be used as a postvisit scale, measuring efficacy experienced directly after the visit.

### 7.2.6 Statistical Analysis

Descriptive statistics were used to characterize the sample and to analyze the process measures. Differences between groups were analyzed using *t* tests and chi-square tests, where appropriate. To analyze short-term effects, linear regressions were conducted to test for differences in experienced efficacy measured at t1 between the control and intervention groups, adjusting for the previsit PEPPI score. To analyze long-term effects, multilevel regressions were conducted to test for differences on the PEPPI scale between the control and intervention groups at t2 and t0. The analysis of the open questions was performed using MAXQDA 11 software [35]. Other process and outcome data were analyzed with Stata 13.

## 7.3 Results

### 7.3.1 Participant Flow

A total of 146 potential participants registered (*uptake*) of which 97/142 (68%) patients met the inclusion criteria and signed the informed consent form (*dose delivered*; Figure 3). This group included 5 patients who were not diagnosed with malignant lymphoma but with a hematologic malignancy with a comparable impact (eg, chronic lymphocytic leukemia or multiple myeloma).

Of the 49 potential participants who were not included, 4 were excluded by the researchers. The remaining 45 did meet the inclusion criteria but did not return the

informed consent form. Compared with these 45 patients, the 97 participants had a significantly higher level of education, were more likely to be a member of a patient organization, had a longer elapsed time between diagnosis and registration, and were more likely to have had or started treatment (Table 3).

All 97 patients in the RCT registered their first consultation date, which was a precondition for being sent the previsit questionnaire (Q0). Subsequently, the *participation rate* was 90% as 87/97 patients completed Q0 and were marked as participants. Compared with the nonparticipants (N=10), the 87 participants had a higher level of education and used the Internet on a more regular basis. After having completed Q1, a total of 76 participants registered a second consultation date and 52 participants a third consultation date as well. There was no significant difference between the control and intervention groups in the proportion registering multiple consultations. Because not every participant had a second or third consultation planned within the participation time span (1 year after registration), the analysis of the outcomes is based on the first consultation only.

### 7.3.2 Process Evaluation

The identified process results that facilitated correct interpretation of the outcomes were part of the delivery domain (eg, fidelity, reach; see Table 2) and user-program interaction domain (eg, exposure, use of different components; see Table 2), in addition to the benefits perceived by the patients.

**Table 3** Background characteristics and outcomes.

Variable	Value	Registered N=142	Randomized N= 97	Participant N=87	Control N=32	Intervention N=55
<b>Age (at registration)</b>	mean years (sd)	57 (14)	55 (13)	56 (13)	56 (14)	55 (13)
<b>Sex, n(%)</b>	male	63 (44%)	40 (41%)	34 (39%)	14 (44%)	20(36%)
<b>Education<sup>a</sup>, n(%)</b>	Low	16 (11%)	6 (6%)	2 (2%)	2 (6%)	0
	Medium	39 (27%)	23 (24%)	19 (22%)	7 (22%)	12 (22%)
	High	89 (61%)	68 (70%)	66 (76%)	23 (72%)	43 (78%)

- table 3 continues -

- table 3 continued -

Variable	Value	Registered N=142	Randomized N= 97	Participant N=87	Control N=32	Intervention N=55
<b>Member of a patient organisation<sup>b</sup></b> n(%)	Yes	71 (50%)	60 (62%)	56 (64%)	16 (50%)	40 (73%)
	No	70 (49%)	37 (38%)	31 (36%)	16 (50%)	15 (27%)
<b>Internet use<sup>c</sup></b> n(%)	daily	128 (90%)	90 (93%)	90 (93%)	29 (91%)	52 (95%)
	weekly	10 (7%)	6 (6%)	6 (7%)	3 (9%)	3 (5%)
	monthly	2 (1%)	1 (1%)	0	0	0
<b>Disease related information</b>						
<b>Diagnosis,</b> n(%)	Hodgkin lymphoma	31 (22%)	22 (23%)	20 (23)	5 (16%)	15 (27%)
	Non-Hodgkin lymphoma	105 (74%)	70 (72%)	63 (72%)	26 (82%)	37 (67%)
	other	6 (4%)	5 (5%)	4 (5%)	1 (3%)	3 (5%)
<b>Disease related information</b>						
<b>Type<sup>b</sup>, n(%)</b>	indolent	57 (40%)	38 (39%)	35 (40%)	13 (41%)	22 (40%)
	agressive	41 (29%)	26 (27%)	23 (26%)	8 (25%)	15 (27%)
	combination	13 (9%)	10 (10%)	8 (9%)	4(13%)	4 (7%)
	not known (yet)	30 (21%)	23 (24%)	21(24%)	7(22%)	14 (25%)
<b>Time elapsed since diagnosis</b>	mean years (sd)	5,4 (7,7)**	6,5 (8,3)*	6.2 (5.5)*	3.2 (3.7)	8.0(10.0)
	< 1 year	42 (30%)	24 (25%)			
	> 1 year	100 70%)	73 (75%)			
<b>Treated, n(%)</b>	Yes	121 (86%)	89 (92%)	79(91%)	4 (13%)	4 (7%)
	No	20 (14%)	8 (8%)	8 (9%)	28 (88%)	51 (93%)

- table 3 continues -

- table 3 continued -

Variable	Value	Registered N=142	Randomized N= 97	Participant N=87	Control N=32	Intervention N=55
<b>Current status<sup>b</sup>, n(%)</b>	awaiting research results or treatment (plan)	19 (13%)	9 (9%)	9(10%)	4 (13%)	5 (9%)
	currently getting treatment	33 (32%)	22 (23%)	19 (22%)	8 (25%)	11 (20%)
	wait-and-see	36 (26%)	26 (27%)	25 (29%)	9 (28%)	16 (29%)
	remission	53 (38%)	40 (41%)	34 (39%)	11(34%)	23 (42%)
<b>Confidence in communication (PEPPI<sup>d</sup>)</b>						
<b>Perceived Pre-visit (t0)</b>	range 10-50 (Cronbach's alpha 0.94)	/	/	20.5 (6.3)	20.3 (6.0)	20.7 (6.4)
<b>Experienced Post-visit<sup>e</sup> (t1<sup>1</sup>)</b>	range 10-50 (Cronbach's alpha 0.93)	/	/	16.5 (7.8)	15.9 (6.7)	16.9 (8.3)
<b>Perceived after &gt; 3 months<sup>g</sup> (t2)</b>	range 10-50 (Cronbach's alpha 0.93)	/	/	19.3 (5.4)	19.2 (6.4)	19.3 (4.7)

<sup>a</sup> Classification according to the guidelines of Statistics Netherlands.

<sup>b</sup> One missing.

<sup>c</sup> Two missing.

<sup>d</sup> PEPPI: Perceived Efficacy in Patient-Physician Interactions.

<sup>e</sup> N/A: not applicable.

<sup>f</sup> Ntotal=78, Ncontrol=28, Nintervention=50.

<sup>g</sup> Ntotal=57, Ncontrol=24, Nintervention=33.

Regarding the delivery domain, we concluded that the publicity actions were conducted as planned. On the whole, the intervention was indeed used as a stand-alone program; most participants did not need any help or reminders from the researchers. The questions they asked (mainly by email) concerned problems with logging in or study questionnaires that were not yet accessible. For the first

consultation, 18 of the 97 randomized patients received at least one reminder to complete their previsit questionnaire.

We noted one issue regarding the “fidelity” that may have influenced outcomes. At registration, patients had to provide the date of their upcoming consultation. Of the potential participants who did this, 44/138 (32%) had their consultation planned within a fortnight. These patients were less likely to participate in the study (59%) compared with the patients who had their consultation later (76%).

Regarding the user-program interaction domain, we report the actual use of the different intervention components that may have influenced the outcomes. Of the participants assigned to the intervention group, 55/63 (87%) completed Q0 and had access to PatientTIME. This group viewed on average 6 (SD 3.5) of the 10 selected video fragments before their first consultation. Of all the fragments they watched, 76% were viewed from beginning to end. The QPS was used to write down questions, physical complaints, and concerns by 20/55 (36%) of the participants who had access to it. Of the intervention audio group 9/29 (31%) participants reported after consultation that they had recorded their visit, 13/29 (45%) reported that they had not, and 7/29 (24%) did not complete this question. Of the participants who did not record their consultation, 8/13 said that they decided that they did not want to make the recording, 2/13 said the HCP did not give permission, 2/13 said they did not want to ask the HCP and 1/13 forgot the recording device.

Regarding the “usability,” 50 intervention group participants completed the System Usability Scale questionnaire at Q1, revealing an average satisfaction score of 73 points (SD 16) on the 0-100 scale, which is considered “good” according to the study by Bangor et al [36].

As for perceived benefits, in the intervention group, 46/50 (92%) participants completed the open question “Did you benefit from the website?” at t1. The positively coded answers (59%) explained that (1) the website was instructive, insightful, or helpful for the preparation of a clinical consultation; (2) the website created awareness about the importance and role of communication; and (3) participants recognized the scenarios, which gave them the feeling that they were doing all right.

*“I’ve been thinking somewhat more about the questions I was going to ask the medical specialist.”...“It makes you more aware of yourself, but also of the doctor’s role.”*

The negatively coded answers (41%) referred to (1) bugs in the questionnaire or usability problems in the website and (2) the fact that the information did not add

anything to what was already known or experienced.

*“Not that much. I have the idea that I am already quite outspoken during the consultations with my oncologists.”...“Not much because I have a good relationship with my physician. I can discuss everything.”*

### 7.3.3 Outcome Evaluation

The results on the PEPPI scale at t0 and t2 (Table 3) were skewed to the lower scores, reflecting a group of patients with a high level of self-confidence about interacting with their HCP. The same skewed trend was visible at t1, reflecting a group of participants who were well able to reach their goals.

There were no differences on the PEPPI scale between the control and intervention groups at baseline (t0,  $P=.78$ ). Directly after the consultation (t1), there was no difference between the control and intervention groups in the way they experienced their efficacy during the consultation (controlling for the previsit PEPPI score). The results remained the same when controlling for sex, the level of education, and time since diagnosis.

Comparing the PEPPI score at t2 with the PEPPI score at t0, the control group showed a small improvement in the level of perceived efficacy. This improvement ( $-0.38$  points) was not significant ( $P=.69$ ). The intervention group also showed an improved level of perceived efficacy. This improvement ( $-1.97$  points) was significant ( $P=.02$ ). The interaction effect ( $-1.59$ ), however, was not significant ( $P=.20$ ), indicating that the improvement solely as a result of the intervention may not be significant. In addition to this primary analysis, we did not find an association between the PEPPI outcomes and the number of video fragments watched.

## 7.4 Discussion

### 7.4.1 Overview

In this paper, we described an integrated process and outcome evaluation of the Web-based intervention PatientTIME. PatientTIME was developed with the aim of helping patients with their communication during clinical consultations. With the process evaluation, we aimed to sketch the context in which the outcome evaluation was performed. The process evaluation was also used to obtain input on how to improve the intervention and its reach before making the intervention publicly available. In the outcome evaluation, we focused on the patients' perceived confidence in interacting with their HCP.

#### 7.4.1 The Process Evaluation

As a result of the process evaluation, we identified a substantial number of delivery and interaction aspects that will help to improve the functionality of PatientTIME and its reach. Looking at the delivery, we want to highlight the recruitment process.

The chosen method may resemble how patients are informed in practice about publicly available Web-based interventions, but despite the various publicity actions during the recruitment period, this approach did not appear to be enough to recruit a large, diverse group of patients for the study (see also Trial Participants section).

The patient-program interaction evaluation showed how the different PatientTIME elements (video fragments, QPS, and consultation audio recordings) were used. The core content of the intervention, the video fragments, was well used. The percentage of fragments viewed entirely (76%) may even be an underestimate (fragments were only logged as “ended” when the screen switched back to start).

The QPS was used less frequently, and slightly less compared with other studies that evaluated the use of open QPS tools in oncology care [37,38]. We do not know if the limited use was due to the design of the QPS, the fact that patients found it difficult to articulate questions, or the fact that patients preferred to make their notes on paper. Albada et al found that patients need to be motivated to use a QPS. Information about why and how to use the QPS could have been made more explicit in the PatientTIME intervention [37]. In the intervention audio group, more than half of the participants did not record their consultation on audio. There appeared to be a variety of obstacles. Other studies show that cancer patients highly value consultation audio recordings and that the majority benefit from listening to the consultation afterward [39,40]. However, in these studies the HCP facilitated the recording, whereas in our study patients were encouraged to take the initiative. We may have failed to provide sufficient information to remove existing obstacles, or the fact that it was part of a trial may have caused patients to be reluctant. To conclude, the QPS and audio recording options should be improved in the PatientTIME intervention.

More than half of the intervention group patients explained that the intervention helped them prepare for a clinical consultation, created awareness, and/or reinforced their existing communication skills. Patients who reported no benefit explained that they already had a good understanding with their HCP, had a lot of experience, or considered themselves as sufficiently participative and empowered already.



### **7.4.2 The Outcome Evaluation**

Looking at the data on confidence in interaction, we found a trend indicating that in the long run, patients with access to PatientTIME scored better on the perceived efficacy scale than patients without access. Differences were, however, small and we did not reach our aim of an improvement of 5 points. Therefore, we cannot conclude at this stage that the intervention positively influenced participants' confidence in their ability to talk with their health professionals.

### **7.4.3 The Results in Perspective**

The strengths and limitations related to the study and intervention put the results in perspective and illustrate our lessons learned. We identified four important aspects.

#### **Trial Participants**

The participants were mainly more educated, experienced patients who were already quite confident in their ability to talk with HCPs. It is a well-known phenomenon in eHealth research that patients with a high level of education are overrepresented in these studies [41,42]. However, a recent study in the Netherlands revealed that the majority of health care users are using the Internet to get information about care and health [43]. This makes it reasonable to assume that a broader group will find PatientTIME when it becomes publicly available. For the outcome evaluation, it is therefore a limitation that less experienced patients (patients who had only recently been diagnosed) and patients with a low initial confidence in their ability to interact were not well represented.

The possible explanations for this are (1) we did not reach them, the idea of a communication support tool did not appeal to them, or (3) they did not want to be involved in a research project. Insight into the reach of the intervention is limited because of the lack of information about patients who read about the intervention but decided not to register for participation. The second explanation seems unlikely given the findings of a recent study among patients with a chronic illness (including cancer patients) that revealed that a considerable number (39%) are interested in communication support [44]. Participating in a study like this demands much more from patients than only using the PatientTIME intervention. We received many questions about the consultation audio recording in particular and patients had concerns about this component. All these extra elements may have made patients reluctant to take part.

## **Outcome Measure**

The participants in this study appeared to be highly confident in their ability to talk with the HCP at baseline, which left little room for improvement (ceiling effect). On the one hand, this suggests that we reached a group who largely did not need support in communication. On the other hand, these patients did enroll for the study and the core information in the intervention tool was well used. This indicates that these patients were interested in improving their communication skills. Perhaps they saw a mismatch between their preferred role and their behavior in the consultation room. This casts doubts on our decision to measure effectiveness with the PEPPI questionnaire only. Bensing et al reported that patients' behaviors in the consulting room are not necessarily a reflection of their self-reported preferred behavior [45]. Because we did not observe the consultations, we cannot describe participants' actual behavior or how PatientTIME may have influenced this. Although the PEPPI questionnaire is a good measure for tracking confidence in medical communication, observations of actual communicative behavior can be a valuable addition. Moreover, the lack of power limits the usefulness of the PEPPI results, as the control group did not reach the required 50 participants. It would also have been interesting to have the patients complete the PEPPI questionnaire again immediately after viewing the PatientTIME content, to measure if their level of confidence had changed as an immediate result.

## **The One-Sided Intervention Approach**

PatientTIME was solely focused on patients, without the interference of or intervening in the communication style of the HCPs. Butow et al found that their patient-targeted communication intervention was only effective when the patient consulted a clinician who endorsed the intervention [46]. The one-sided approach used in PatientTIME may have decreased the potential reach and effect.

## **Implicit Trial Effects**

Two trial effects were identified that may have influenced outcomes. First, regardless of whether participants were allocated to the intervention group or the control group, it is likely that the mere fact of participating in a communication study highlighted the importance of the participant's role in medical communication. Increased awareness of being observed in a trial setting may have affected outcomes (pre- and postvisit), which limits generalizability (Hawthorne effects). Second, the relatively lengthy time between registration and getting access to the intervention

tool (because study information needed to be provided and informed consent obtained) delayed the inclusion process. This may have excluded patients who were looking for communication support shortly before their planned consultation. Ideally, access should be given immediately.

#### **7.4.3 Conclusions**

A considerable number of patients indicated that the intervention was helpful in preparing for a clinical consultation, created awareness about the importance of communication, and reinforced their existing communication skills. These are valuable findings as such. However, at this stage we cannot conclude that PatientTIME improves patients' confidence when interacting with health professionals. By integrating a process evaluation and an outcome evaluation in this way, we were able to demonstrate which elements of PatientTIME were used and appreciated, even though they did not lead to measurable changes in communication self-efficacy.

#### **7.4.4 Future Research**

We identified three themes for future research. First, when evaluating the effectiveness of stand-alone Web-based interventions like PatientTIME, it may be worthwhile to consider research methods that allow the intervention to be dynamic, rather than freezing it in a certain state. In practice, Web-based interventions also need to be optimized continuously. With a more dynamic approach, intermediate test results can be used to improve the intervention and new versions of the intervention can be released during the evaluation phase. Second, when evaluating stand-alone interventions in a trial setting, the involvement of HCPs as informants might be crucial as a means of reaching a more diverse group of patients. More than half of the intervention group patients explained that the intervention helped them in the preparation for a clinical consultation, created awareness, and/or reinforced their current communication skills. Patients who reported no benefit explained that they already had a good understanding with their HCP, had a lot of experience, or considered themselves as sufficiently participative and empowered. Finally, it will be interesting to continue monitoring the use and effectiveness of PatientTIME once it is publicly available in order to provide input for other interventions and to keep PatientTIME up-to-date.

**Acknowledgments**

The authors would like to thank all participants and Hematon for their kind cooperation, the Alpe d'HuZes program of the Dutch Cancer Society for funding this study (grant number NIVEL 2010-4747), and Jedidja Verboom for her help coding the qualitative data. The funders had no role in this study.

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# 8

## Summary and general discussion

The overarching aims of project PatientTIME were 1) to enhance (out-) patients' conversational contributions to their consultations in oncology care, and 2) to examine the feasibility of granting patients more control in the execution of a research and development project. As part of the applied participatory research and development protocol, we conducted a series of studies in cooperation with patients and health care professionals and a web-based, pre-visit communication tool for patients was built. In this last chapter, we summarize the findings of our studies (§8.1). Subsequently, we reflect on the PatientTIME project by discussing overarching intervention- and study-related issues (§8.2 and §8.3). We conclude with considerations for future research that evolved from these reflections (§8.4).

## 8.1 Summary of Findings

### 8.1.1 Needs assessment (chapter 2)

*What helps and hinders patients diagnosed with malignant lymphoma in their communication during medical consultations?*

Before starting the development of the actual intervention components, we wanted to learn from the experiences of patients during clinical consultations. We used a qualitative research method derived from the context mapping framework, to inquire about barriers and facilitators patients perceive when communicating with their health care professionals. The qualitative data obtained via probes and (group) interviews were analysed with MAXQDA software.

The study resulted in a long list with factors that hindered patients to communicate effectively. A second list was created with the strategies patients applied aiming to improve communication. From the patients' viewpoint, communicating effectively appears to depend on their own attributes (e.g. emotions), the health care professionals' attributes (e.g. attitude) and external factors (e.g. time pressure).

We searched for patterns to explain when the barriers influence communication predominantly and identified three 'patient communication states' as patients being; (i) overwhelmed, passive; (ii) pro-active, self-motivated; and (iii) proficient, empowered. Patients seem to behave differently in these three communication states. The participants in this study frequently discussed the concept of awareness; being aware of your own intentions and of the benefits that can be gained when discussing preferences and concerns.

The findings may support health care professionals to tailor the provision of support and information and remove communication barriers accordingly. Additionally, the results provided input for interventions to support patients in effective communication, such as PatientTIME.

### **8.1.2 Participatory development (chapter 3)**

*How can we involve (seriously ill) patients in the development, evaluation and implementation phase of a patient-targeted communication intervention?*

To develop a patient-targeted intervention, we needed a way to give patients the opportunity to guide and inspire the development, evaluation and implementation process. At the same time, we wanted to build on previous knowledge and evidence based working mechanisms. We chose the Intervention Mapping (IM) protocol as a theoretical backbone because it links decisions, final materials, and activities to theory. Participatory methods inspired by the participation ladder and user-centred design thinking were integrated throughout this entire IM framework. In this way we aimed to try-out a bottom-up inspired protocol.

Patient involvement in the PatientTIME project was operationalized in three ways. First, we set up a close collaboration with Hematon (former LVN). After they had put their patients' need for support in communication forward, we involved them in the design of the research proposal. During the project, Hematon informed and supported patients, championed patient interests and an agreement was made about implementation options after the evaluation phase would be finished. Second, patients were included as research partners, who were involved throughout the entire project. They were equal partners next to the researchers and clinicians by having an agenda setting and decision-making role. Their involvement ensured a continuous patient-centred view. Third, patient service users were involved on different levels, during the different protocol steps. The patient service users were included next to the patient research partners, to give fresh, new insights on the different protocol steps. They were for example included during the needs assessment phase with context mapping techniques, or they were asked to perform a usability test or pre-test the questionnaires.

By recruiting patients for different purposes (e.g. preparation, development, evaluation, implementation) and on different levels of involvement (e.g. advisory board members, counsellors, pre-testers), we were able to compose a diverse group. Important to keep in mind is that the participating patients represent a self-selected convenience sample, as patients voluntarily signed up to contribute to the

study. We experienced that organizing patients' involvement early in the project, as well as flexibility in terms of planning and setup were preconditions to allow for involvement of (seriously ill) patients on a continuous basis.

### **8.1.3 Modelling communication strategies (chapter 4)**

*Are the modelled strategies remembered as intended and is the context not too overwhelming?*

For the central content of the PatientTIME intervention, 58 short video fragments of simulated clinical consultations were created. The fragments were based on patient narratives, in which the communication behaviour and strategies were embedded. Narratives provide illustrative examples of patients' experiences. Identification with narrative characters has shown to be important to recall the central information of educational clips<sup>1</sup>. This promotes the use of realistic simulations. Yet, the context of the communication and identification with the (video) patient can also evoke (sub)conscious emotional arousal<sup>2</sup>.

PatientTIME is used without the feedback or presence of a professional. Therefore it is important to investigate the emotional impact of the educational clips thoroughly<sup>3</sup>. A moderate increased level of arousal is preferred to increase the learning capacity. However, too much arousal may decrease the learning capacity and may cause distress, which should obviously be avoided for ethical reasons. We investigated therefore the influence of watching three educational patient-provider interactions on 75 analogue patients' emotional arousal and information recall. Emotional arousal was measured with physiological responses (electrodermal activity and heart rate) and self-reported arousal. A moderate increased level of physiological arousal was measured but not too much to inflict emotional distress. Recall of information was within the pursued range. Hence, physiological arousal is not expected to hinder the goals we aim for with PatientTIME.

Although we did not find large physiological responses, we think it is important that developers, researchers and health care professionals remain attentive to the self-reported (conscious) and hidden (subconscious) emotions evoked by the context of educational video clips presented in self-help interventions.

### **8.1.4 Consultation audio-recordings (chapter 5)**

*What are the experiences and views of health care professionals in oncology care regarding consultation audio-recordings?*

Giving patients the opportunity to listen back to their consultation is a widely researched topic as it is intended to support patients in their communication with health care professionals. Despite the benefits of this intervention, providing audio-recordings to patients has not yet become common practice in (oncology) clinics<sup>4, 5</sup>. Current developments enabling and motivating patients to record the consultation are leading to resurgence in the use of audio-recordings. Patient associations have recently started to encourage patients to record their clinical consultations. Smartphones and tablets enable patients to make audio-recordings in an easy and accessible way. At the same time, new electronic patient records facilitate the inclusion of audio-recordings.

In the PatientTIME evaluation, we had incorporated a (pilot) study stimulating participants to make an audio-recording of their clinical consultation themselves, to get insight in their experiences. But we were also interested in the experiences of health care professionals, who have to deal with the abovementioned developments.

Via a survey, 215 Dutch health care professionals working in oncology care shared their experiences with consultation audio-recordings and their perceived risks and influence on the patient-provider interaction. The majority of the respondents had experience with audio-recordings. Most respondents (would) cooperate if a patient asks for permission to record the consultation. There are widely differing views on the perceived influence that the audio-recordings have on the consultation process. Professionals who are in favour of the use of audio-recordings seem to embrace the evidence-based benefits for patients, and mention the positive influence on their patients. Opposing arguments relate to the perceived lack of control, the unclear legal status of the tapes and the feeling of inhibition influencing the professionals' communication style.

The detailed and strongly worded clarifications to the answers demonstrate that consultation audio-recordings are a topical issue. The current study demonstrates widespread support for the use and implementation of consultation audio-recordings in clinical consultations. However, the concerns that exist among health care professionals need to be tackled in order to increase transparency, as audio-recordings are expected to be used increasingly.

### **8.1.5 Through patients' eyes (chapter 6)**

*What are the patients' preferences and perceived performance regarding the communicative behaviour of their health care professionals during haematological consultations?*

To get a better understanding of how communication in haematological consultations can be improved, we studied patients' preferences and perceived performances regarding the communicative behaviour of their health care professional. Additionally, the possible mediation of PatientTIME was analysed. Increased awareness of the importance of communication may have positively influenced patients' perceptions as a 'side-effect' of the PatientTIME. But we also hypothesized that the intervention could raise expectations and caused a more critical attitude towards the doctor<sup>6-8</sup>. Within a controlled pre-post-test design, 78 clinical consultations were analysed.

Patients considered both affective and instrumental communication aspects important. In agreement with comparable studies in general practice and oncology care, participants in the current study considered pre-visit both affective and instrumental communication aspects important<sup>9-12</sup>.

Post-visit, the affective communication behaviour of the health care professionals met the patients' pre-visit preferences well. In the information exchange more variability and discrepancies were found. Overall, the online intervention did not seem to influence the participants' perceived communication performance of their health care professional much.

To further improve the communication during clinical consultations, health care professionals should (continue to) inquire about patients' expectations, especially during the exchange of information and advices. At the same time, patients should be supported (for example by the health care professional or patient-targeted communication interventions) to express their preferences at the start of the consultation.

### **8.1.6 Process and outcome evaluation (chapter 7)**

*(How) do patients benefit from the PatientTIME intervention?*

The aim of this study was to evaluate if and in what way patients benefit from PatientTIME and if it influences their confidence in clinical communication. The intervention was evaluated in a closed randomized controlled trial with continuous recruitment and data collection. On- and offline recruitment methods were used to reach potential participants. According to the guidelines of the Medical Research

Council, the evaluation started with a process evaluation focusing on the delivery, interaction and contextual factors. Subsequently, an outcome evaluation was performed; focusing on the patient's perceived confidence to interact with their health care professionals. A total of 146 patients registered online of which 97 were randomized in the control group (N=34) or one of the two intervention groups (N=63) after providing informed consent. 87 datasets (90%) were available for analysis.

More than half of the intervention group patients explained that the intervention helped them in the preparation of a clinical consultation, it created awareness about the importance of communication and reinforced their current communication skills. In the post-test, the control group showed a small, non-significant improved level of perceived communication efficacy. The intervention group showed a significant improvement of perceived efficacy. However, the interaction effect was not significant, indicating that the improvement solely as a result of the intervention may not be significant. The central content of the intervention (video fragments) was well viewed, but we did not find an association between the efficacy outcomes and the amount of videos viewed.

A considerable number of patients indicated that the intervention was supportive. We found a trend indicating that in the long run patients with access to the intervention PatientTIME scored better on the perceived efficacy scale than the patients without access. However, at this stage we cannot conclude that PatientTIME improves patients' confidence in interacting with professionals. Further research is needed that preferably includes participants with a low confidence in their ability to interact with the health care professional and patients who are less experienced in the health care system (shorter after being diagnosed).

### *Lessons learned from the PatientTIME project*

## **8.2 Intervention-related reflections**

### **8.2.1 The intervention components of PatientTIME**

PatientTIME involved a number of different strategies aiming to enhance patients' communication skills. The tailored selection of video fragments was the central

content of the intervention. Additionally, an open question prompt sheet (QPS) and an option to store and listen back to consultation audio-recordings were provided.

### **Tailored video fragments**

The video fragments in PatientTIME were well viewed. The conversational communication style of the video-patients may have contributed to this. Recent studies reveal that the use of video fragments with such a conversational style is the best way to present web-based information and that personalized videos can enhance website satisfaction and information recall<sup>13, 14</sup>. Tailoring the selection of video fragments to the viewer's diagnosis and communication needs, may have contributed to the extent to which viewers could identify with the video patient<sup>1, 15</sup>.

Multimedia interventions can easily be tailored to the user's preferences and needs. According to the Elaboration Likelihood Model, personally relevant information enhances thoughtful consideration and evaluation<sup>16</sup>. This cognitive process can increase attention rates<sup>17</sup> and compared to generic information, tailored information has been associated with increased effects on behavior change<sup>18</sup>. However, at this stage we do not know if patients changed their communicative behavior in the consultation room as a result of watching the PatientTIME videos. Video-observational studies can give insight in patient's actual communication behavior, which could be an interesting next step to research.

### **Consultation audio-recordings**

Implementation of consultation audio-recordings via patients will only be feasible when both parties (health care professionals and patients) endorse this new approach. To follow the developments in the use of consultation audio-recordings and to find out how the implementation can advance patient-professional communication, experiences and views of health care professionals in oncology care were studied (chapter 5). At the same time, we encouraged a (pilot) group of participants in the PatientTIME study, to audio-record their own clinical consultation and studied their experiences. These patients were provided with a small audio-recording device and information about how to record the consultation. Subsequently, patients could upload and listen back to their recording via their PatientTIME account. We monitored also their experiences and views.

Results of these studies show that both groups have concerns that impede implementation, for example about the unclarity of the medico-legal status, privacy



issues and misapprehensions about the (evidence-based) benefits. A minority of the health care professionals even prohibits their patients to record the consultation.

Comparable with previous studies, PatientTIME participants who recorded their consultations were very positive about listening back<sup>4,19</sup>. However, many participants had various reasons why they did not want to take part in this part of the study and for a considerable number of patients it was a reason to decline participation in the overarching study.

On March 10th, 2016, the Dutch Minister of Health, Welfare and Sport recommended *patients* in an official statement to audio-record their clinical consultations<sup>20</sup>. Reactions from health care professionals to this statement (Box 1)<sup>21</sup>, matched the concerns we found in our study.

**Box 1.** Published reactions from professionals on the statement of the Ministry to encourage patients to make audio-recordings<sup>21</sup>.

*"I have some experience with this, and my advice: do not make a fuss about it. Turn it into a win-win situation" (psychiatrist)"*

*"With those audio-recordings, you will also get the medicolegal misery on your shoulders" (general practitioner)*

*"I have great misgivings about the effects and value of the recordings" (psychiatrist)*

As a result of these developments on governmental level and the available technical possibilities that make it easy to record a clinical consultation, audio-recordings are expected to be used increasingly by patients. However, to take this implementation approach a step further, transparent information and guidelines are needed to inform and instruct both patients and professionals. To inform patients better via the PatientTIME intervention, we could improve the information about the evidence based benefits, as the information is now mainly focused on how to make the recording. Other strategies to inform patients should be developed in collaboration with patient associations and patient advocates. Also health care professionals can play an important role in encouraging patients to record the consultation, especially when it concerns 'new' cancer patients who are not yet familiar with clinical consultations.

### Question prompt sheet

In the PatientTIME intervention, an open QPS was provided which patients could print or e-mail to themselves. The QPS tool was used slightly less compared to two

studies that evaluated the use of an open QPS in oncology care<sup>22, 23</sup>. QPS interventions have proven to be effective in improving communication and cognitive and psychological outcomes of cancer patients<sup>24</sup>. However, not everyone will have the need to use, or feel supported by a QPS. Participants in the PatientTIME study were merely high-confident in their ability to interact with their health care professional at baseline. They may not all felt the need to use a QPS. For patients who could benefit from a QPS, Albada et al (2011) suggested that patients need to be motivated to formulate their own questions and that this advice should be explicit and easy accessible. In PatientTIME, we could provide more explicit information about the (evidence-based) benefits of using a QPS. Another strategy to increase QPS use, may be the inclusion of example questions, like most evaluated QPS interventions do<sup>25</sup>. This may support patients who have difficulties formulating questions. In that case we must carefully select topics and still leave the option open for other topics.

### 8.2.2 The patient targeted approach

The PatientTIME intervention focusses on supporting the patient in medical communication. During the research and development phases, we noticed that this appeared to be a topical issue. We got many (sometimes strongly opinionated) remarks and questions from patient (advocates) and health care professionals, positive but also negative;

*“Why bothering seriously ill people with communication issues”*

*“You should teach the doctor how to communicate”*

Even though most training programs focus on communication skills for health care professionals and they are the ones who are responsible for the course and content of the clinical consultation, there are reasons why we think we should also focus on ‘the other side of the table’.

Most patients have the need ‘to know’ and the need ‘to feel known’<sup>26</sup>, but in clinical practice they often find it hard to express their preferences and needs<sup>27</sup>. Despite the current increased focus on shared decision-making, patient centeredness and patient empowerment, it is not evident that patients act more assertive during the medical consultation. Recent research shows that concerns are still rarely voiced openly and / or spontaneously<sup>28</sup>. Butalid et al (2014) found in a historical cross-sectional study that primary care patients have become somewhat more explicit, but not more extensive in their expressiveness<sup>29</sup>. Also, when patients express that they prefer to participate actively, it does not mean that they act

accordingly<sup>30</sup>. In addition to the existing training for professionals, we therefore think it is important to support patients as well.

PatientTIME focusses *solely* on the communication skills of patients, whereas communication implies an interaction between different actors and influenced by multiple factors, including the environment, goals and the behaviour of all participants<sup>31, 32</sup>. Brandes et al (2015) concluded in their study among cancer patients, that these patients perceive influential communication barriers (e.g. perceived lack of time) they cannot overcome themselves<sup>32</sup>.

In this context, the one-sided approach applied in PatientTIME can be seen as a limitation in the attempt to improve patient-professional communication. Endorsement of the health care professional, or integrating a 'health care professional-part' in the intervention, may improve the effectiveness. How this approach should be operationalized, needs further research and creativity, as existing examples show mixed results. Butow et al (2004) found positive outcomes with their patient communication support only when clinicians 'endorsed' the intervention<sup>33</sup>. However, a review evaluating the effectiveness of multiple patient-targeted interventions, found that the inclusion of clinician training was ineffective<sup>34</sup>.

### **8.2.3 The Internet as medium to deliver patient-targeted interventions**

PatientTIME makes use of the Internet to inform and prepare patients for their hospital visit at home. The Internet has become an important source of information for patients<sup>35</sup>. A recent study in the Netherlands reveals that the majority of health care users is using the Internet to get information about care and health<sup>36</sup>. The fast growing audience reach of the Internet (especially among elderly) and the endless technical possibilities create many opportunities. The increase in the use of (blended) web-based care and support will be inevitable.

To implement eHealth interventions successful, special attention is needed for the frequently mentioned problems with *attrition* and with the *uptake*<sup>37, 38</sup>. We also experienced this with the PatientTIME intervention.

Attrition is defined as the intended completion of a range of modules with increasing challenges to complete. In PatientTIME, attrition could not be measured this way, because patients were not asked to follow a range of modules. We did look, however, to how the different intervention components were used. Logfiles can help to monitor these interactions.

Regarding the uptake of PatientTIME, the intervention appeared to reach mainly higher-educated, experienced patients, who were already quite confident in their ability to speak with health care professionals. This biased group challenges the generalizability of our results to lower educated and less experienced patients. Our strategies appeared to have been insufficient to reach a diverse group of patients, a well-known phenomenon in eHealth research<sup>38</sup>. For future projects, we recommend to examine how we can reach specific groups (e.g. lower-educated, patients with a low confidence in their ability to interact with professionals, lower health literates) that may benefit from online communication support. For haematology practice, it may be interesting to focus on reaching patients who just got diagnosed with a more acute and aggressive disease.

## 8.3 Study-related reflections

### 8.3.1 eHealth development and effect evaluation: consecutive or parallel processes?

Traditionally, a health intervention is developed, locked-down and next the effectiveness is evaluated with (preferably) a randomized controlled trial; the classical design of experimental studies. To test a single working mechanism, this controlled setting may be suitable. The context in which web-based interventions are delivered, is everything but static. Content and functionality are continuously adapted to meet the dynamic context which includes the fast changing needs and expectations of users. The continuous evolvement of web-based programs is in contrast with the health interventions that are locked down for a considerable duration to evaluate their effectiveness.

Like other studies report, we experienced the limitations of testing a frozen intervention in a controlled setting, while the environment is continuously evolving. As soon as the trial started, we got information about user-interactions with the different intervention components (via logfiles) and feedback from participants (via e-mail). Although we altered some minor elements (and to this sense we applied a more pragmatic trial), the research design prevented that we evolved the program as a result of intermediate feedback and results. Recently, the scientific and public value of evaluating locked down web-based interventions is questioned<sup>39</sup>. Mohr et al (2015) suggests “Trials of Intervention Principles” as an alternative evaluation method that allows the intervention to evolve during the evaluation<sup>39</sup>. In this way,

development and evaluation will be more integrated which will change the collaboration between developers and researchers.

Another framework that may be interesting to use when developing web-based health interventions is the agile working principle 'scrum', originated from software development<sup>40</sup>. In this method short dynamic cycles of analysis, design, implementation and evaluation allow all stakeholders to influence the intervention from scratch. A first version of the intervention is delivered early in the development process and along the way it is adapted and optimized based on intermediate test results.

### **8.3.2 Involving (seriously ill) patients in research and development**

While patient participation is a hot topic in intervention development, the actual involvement of patients is marginal in most projects. It often seems a more symbolic statement and the actual operationalization (how and when (seriously ill) patients are involved) is rarely reported<sup>41,42</sup>. Especially in the field of web-based interventions, it is relatively easy and fast to come up with a program or tool, without leaving the office. But these expert driven (top-down) approaches are more and more indicated as possible cause for the frequently reported attrition and adoption problems<sup>43</sup>.

There seems to become more attention for patient involvement. Today, user (or patient) involvement in research and development is considered one of the elements that influence the success of an intervention. The potential benefits of involving end-users during the development are widely accepted and there is a clear urge for more end-user involvement. BMJ papers started to document patient involvement and they are gradually raising the bar aiming to reach the level where only research papers will be accepted in which patients have been fully involved<sup>44</sup>. In health care, expert-driven development approaches (without the involvement of the targeted group) are often applied<sup>39, 43</sup>. This approach can be quick and cost efficient in the development phase, but it is safe to say that it leaves little room for patients to influence the process or end-result. In the PatientTIME project we used the Intervention Mapping framework as theoretical backbone. This framework was the overarching research and development guide and we applied it in a fairly patient-participatory way. However, we could have done better. We identified the main factors that challenged the operationalization of patient involvement in our project, which may be generalizable to similar projects:

### **A research proposal as a starting point**

Traditionally, when applying for a grant to solve a problem by means of a web-based health intervention, researchers write a research proposal that requires a detailed development, evaluation and implementation plan. The researcher is forced to make a lot of decisions before the project has even started. On the one hand researchers build on existing knowledge and techniques. At the other hand, it challenges the extent to which the targeted patients can truly influence the project. Especially when the proposal concerns an innovative project, there might be less information to build on and the influence of the targeted population can be very important. The required level of detail of a research proposal seems to be in contrast with the increased focus on requirements regarding patient involvement.

### **Time & flexibility**

In the context of (cancer) care, the potential end-users may be seriously ill and it may not always be easy to involve these target groups. After establishing the preferred user involvement, flexibility (and creativity) in terms of planning and study design are a prerequisite in the execution of a project. Also, not for all intermediate steps the targeted end-users need to be recruited. For some purposes, healthy people (as analogue patients) can be a valid substitute (e.g. chapter 4).

### **Different working process**

Involving end-users in the development of a web-based program or involving patients in a research project can be difficult to streamline. Web-developers and researchers have quite different working processes. Accordingly, also the way they involve end-users differs. These working processes need to be aligned when developing and evaluating eHealth interventions.

### **8.3.3 Randomizing patients in eHealth evaluation**

The evaluation protocol of PatientTIME described a traditional RCT with an intervention and control group. The randomization process did not include participants' preference for using web-based interventions or not. Today, the way eHealth interventions are evaluated according to the traditional methods is questioned. The study participant's preferences for a certain type of intervention (or the way it is delivered), is expected to influence low recruitment rates, high drop-out and low attrition<sup>45</sup>. It is even likely that it influences the effectiveness of the intervention<sup>46</sup>. A Patient Preference Trial (PPT) may be an interesting alternative for

the traditional RCT when evaluating web-based interventions. This way of personalizing the research method is relatively new and further research is needed to explore for example the possible randomization procedures and the fields of application.

Not randomizing study participants and following them as a cohort is another way to evaluate a web-based intervention. In this way the effects of changes made during the study can be monitored, which can be an interesting option when evaluating the attrition and uptake of web-based interventions (8.3.1).

## 8.4 Considerations for Future Research

In the PatientTIME project we aimed to advance patient-provider communication via a web-based patient-targeted intervention while involving patients in different research and development phases. We translated our lessons learned to challenges for future research and developments in this field:

- I. The effects of the way health care professionals endorse patient-targeted communication interventions and the way they can be involved, need to be further explored.
- II. The reach of web-based interventions should be improved with strategies focusing on lower empowered patients, lower health literates and patients who were recently diagnosed. Preferably, patients representing these target groups should be included in the development of these strategies.
- III. The ways in which continuous evolvement of web-based interventions can be integrated in effect evaluations should be further explored.

### *The end ...*

*The evaluation of PatientTIME will be completed in 2016. We will analyze the data of patients who participated with a second and third clinical consultation. One of our research questions left is if, and how the use of the intervention changes over time. The content of the intervention will be transferred to the patient association 'Hematon' and will be embedded in their website. Hematon will pay particular attention to the importance of good doctor-patient communication.*

*Building on the lessons learned during the PatientTIME project and previous studies from others, NIVEL set up a new project called 'Luistertijd' in which a communication tool is developed which targets both patients and their health care professional. Luistertijd aims to support older patients with cancer and their health care professionals in reaching effective communication.*

*We also would like to focus upon patients who are diagnosed with an acute hematological malignancy. We want to set up a project to support these patients with the clinical communication shortly after being diagnosed. Another ambition is to enroll PatientTIME for other patient groups. Many communication barriers appear to be not disease-specific and we are therefore now looking at the possibilities to develop a PatientTIME version for patients who live with a chronic kidney disease.*



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## Samenvatting

*Op het moment dat iemand de diagnose kanker krijgt, verandert zijn of haar leven enorm. Zowel de ziekte als de behandeling kan grote invloed hebben op het emotionele, psychische en fysieke welzijn van een patiënt. Een essentieel onderdeel van een leven met kanker betreft de steeds terugkerende gesprekken met de medische specialisten. Dit zijn belangrijke gesprekken, omdat daarin wordt verteld in welke mate de behandeling succesvol is en welke opties er zijn voor het vervolgtraject. Hoe patiënten omgaan met hun ziekte tussen de opeenvolgende bezoeken aan het ziekenhuis, hangt mede af van het verloop van deze gesprekken. Daarom is het voor patiënten belangrijk hieruit zo veel mogelijk informatie en steun te halen.*

## Inleiding (hoofdstuk 1)

In vergelijking met een aantal decennia geleden is in de geneeskunde meer aandacht gekomen voor ‘persoonsgerichte geneeskunde’; een verschuiving van focus op de ziekte, naar focus op de persoon die de ziekte heeft. De rechten van de patiënt zijn in dit kader formeel vastgelegd (Wet op de Geneeskundige Behandelingsovereenkomst, WGBO), waaronder het recht op inzage in dossier, instemming bij beslissingen en een second opinion. Deze veranderingen maken dat patiënten meer of actiever zouden kunnen participeren in het zorgproces. Uit een aantal studies blijkt dat het een actief participerende patiënt beter vergaat. Hoewel bewijs hiervoor niet altijd wordt gevonden, zijn er ook ethische en empirische gronden om een actieve rol van de patiënt aan te moedigen.

Het aannemen van een actieve rol is echter niet altijd gemakkelijk. Tijdens een medisch consult komen veel belangrijke onderwerpen aan de orde. Onder normale omstandigheden kan het al lastig zijn onderdelen van het gesprek goed te begrijpen en te onthouden. Wanneer patiënten te maken hebben met een ernstige ziekte gaan zij (en hun naasten) vaak gespannen en bezorgd een consult in. Er worden vervolgens complexe zaken besproken waar men vaak (nog) weinig kennis over heeft. Ook moeten soms moeilijke keuzes gemaakt worden. Actief deelnemen aan het gesprek is dan niet eenvoudig.



Radboud  
University  
Nijmegen



Wij zijn daarom het project ‘PatientTIME’ opgestart. Het doel van dit project was om patiënten meer grip te geven op de gesprekken met zorgverleners. Het project is uitgevoerd in samenwerking met het Radboudumc, VUMC en patiëntenorganisatie Hematon. Patiënten stonden centraal in dit project en op vele manieren hebben zij (en hun naasten) een bijdrage geleverd aan het ontwerp, de implementatie en de evaluatie van de online interventie die daaruit voortgekomen is.

### Arts-patiënt communicatie

Effectieve communicatie wordt gezien als een belangrijke voorwaarde voor het leveren van goede zorg. Voor de arts is het van belang om biomedische en psychosociale problemen in kaart te brengen en te managen. Voor de patiënt is het van belang om begrepen te worden en te begrijpen wat er aan de hand is. De manier waarop het gesprek met de arts verloopt wordt gerelateerd aan verschillende uitkomsten, zoals tevredenheid over de zorg, ervaren kwaliteit van leven en therapietrouw. De vaak complexe aard van een medisch gesprek en het soms emotionele en gespannen decor, maken het echter niet altijd makkelijk een effectieve vorm van communicatie te bereiken.

De uitdagingen van een goed medisch consult komen binnen de oncologische zorg, waar ernstige biomedische en psychosociale kwesties sterk met elkaar verweven zijn, dagelijks aan het licht. In de diagnostische fase zijn patiënten vaak

*“Soms krijg je een antwoord, en voordat je het weet zit je thuis en denk je, wat moet ik eigenlijk met dit antwoord?”*

overweldigd, gespannen en ernstig ziek. Tegelijkertijd moet er complexe informatie uitgewisseld (en onthouden) worden over bijvoorbeeld behandelopties, medicijngebruik en bijwerkingen. Na de primaire behandeling komen er vaak additionele onderwerpen aan bod, die voor sommige patiënten lastig bespreekbaar te maken zijn. Zo hebben veel patiënten bijvoorbeeld te maken met complicaties van de behandelingen, lange onzekere controleperiodes, angst voor een recidief, psychosociale problemen, et cetera.

### Patiënten in de spotlight

Zowel de arts als de patiënt beïnvloedt het gesprek tijdens een medisch consult. Artsen zijn verantwoordelijk voor het faciliteren van het proces en de inhoud van

het gesprek. In de afgelopen decennia is er binnen onderzoek en onderwijs steeds meer aandacht gekomen voor het trainen van zorgprofessionals in patiëntgerichte communicatie. Patiëntgerichte communicatie vraagt echter ook een actief betrokken patiënt.

Binnen de oncologie lijken veel patiënten zo'n actievere rol in de gesprekken te prefereren, maar in de praktijk blijft hun inbreng vaak beperkt, mede door de vele communicatiebarrières die ze ervaren. Wanneer patiënten hun gewenste rol in het consult goed kunnen voeren, blijken ze meer tevreden met het consult te zijn dan wanneer dit niet lukt. In een Nederlandse studie onder ruim 1300 chronisch zieken (waaronder kankerpatiënten) geeft 46% van de respondenten aan barrières te ervaren die het deelnemen aan een medisch gesprek belemmert. Naast de communicatiestijl van de zorgverlener en omgevingsfactoren, relateren patiënten deze barrières ook aan hun eigen communicatievaardigheden. Bijna 40% geeft aan graag ondersteuning te krijgen om een gesprek goed te kunnen voeren.



*“In het begin weet je eigenlijk niet eens wat je wilt weten.”*

Naast het trainen van professionals, lijkt het in dit licht interessant om ook patiënten te ondersteunen in het voeren van effectieve gesprekken.

De afgelopen jaren zijn er verschillende communicatie-interventies voor patiënten ontwikkeld. Het merendeel bestond uit face-to-face trainingen gericht op gesprekken waarin een behandelplan besproken zou worden. Deze (vaak Engelstalige) trainingen waren meestal niet gericht op een specifieke ziekte.

### **Het PatientTIME project**

Het primaire doel van het PatientTIME project was een patiëntgerichte interventie te ontwikkelen, testen en evalueren, waarmee patiënten hun gesprek met de zorgverlener kunnen voorbereiden. Daarnaast was ons doel om na te gaan of het haalbaar is patiënten zelf een meer actieve rol te laten spelen bij deze processen. Deze overkoepelende doelen hebben geresulteerd in verschillende deelstudies die in de verschillende hoofdstukken van dit proefschrift worden beschreven.

### **Van theorie naar praktijk**

De ontwikkeling van een patiëntgerichte interventie is geen op zichzelfstaande activiteit. Wanneer je in de praktijk iets wilt bereiken met een interventie, is naast de ontwikkeling ook de probleemanalyse, implementatie en evaluatie van belang.



Deze vier domeinen beïnvloeden elkaar en bepalen uiteindelijk het succes van de interventie.

In de literatuur worden probleemanalyses en evaluatiestudies vaak uitgebreid beschreven. Over de ontwikkeling en implementatie is veel minder te vinden, laat staan de manier waarop (ernstig zieke) patiënten betrokken worden in deze processen. Met een participatief proces hebben we binnen PatientTIME geprobeerd de vier domeinen aandacht te geven vanaf de start van het project.

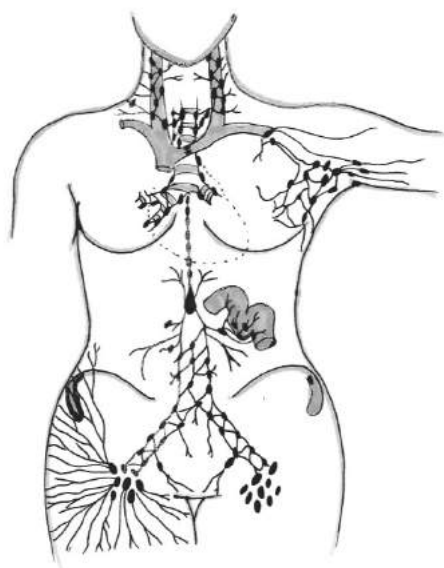
### De doelgroep

De ontwikkelde interventie en vijf van de zes studies in dit proefschrift zijn gericht op patiënten met een vorm van (non-)Hodgkin, ofwel lymfklierkanker (box 1). De studie die in hoofdstuk 5 beschreven is, is gericht op oncologische zorgverleners.

#### Box 1 (Non-)Hodgkin

Bij lymfklierkanker zijn de cellen in de lymfklier ontaard. Lymfomen kunnen op verschillende plekken in het lymfestelsel ontstaan. Er wordt onderscheid gemaakt tussen twee hoofdvormen: Hodgkin en Non-Hodgkin. In Nederland wordt per jaar bij ongeveer 450 mensen Hodgkin vastgesteld. Hodgkin komt onder alle leeftijden voor, maar wordt het vaakst bij jongvolwassenen vastgesteld. Non-Hodgkin is de overkoepelende term voor meer dan 50 varianten (anders dan Hodgkin) van lymfklierkanker. Ook Non-Hodgkin komt op alle leeftijden voor, maar 50% van de patiënten die gediagnosticeerd worden is 66 jaar of ouder. In Nederland wordt per jaar bij ruim 4200 patiënten Non-Hodgkin vastgesteld.

Het verloop van de ziekte verschilt enorm tussen alle vormen van lymfklierkanker. Er zijn zeer agressieve en indolente (traag groeiende) varianten. Logischerwijs verschillen de mogelijke behandelingen ook sterk. De laatste decennia zijn de behandelingen steeds beter geworden en overleven steeds meer mensen de ziekte. Desalniettemin hebben deze 'survivors' vaak voor een lange periode te maken met langetermijneffecten van de ziekte.



Figuur 1 Het Lymfestelsel

## eHealth

Om patiënten te ondersteunen in gesprekken met zorgverleners, hebben we ervoor gekozen om een online interventie te ontwikkelen (box 2). Online interventies worden ook wel 'eHealth' genoemd. eHealth staat voor het gebruik van informatie- en communicatietechnologieën (met name via het internet) om gezondheid en gezondheidszorg te ondersteunen of te verbeteren. Via het internet kan een grote groep mensen bereikt worden. In Nederland had in 2013 97% van de bevolking toegang tot het internet, en 88% gebruikte het internet dagelijks. De PatientTIME interventie is in 2012 ontwikkeld, en tussen 2013 en 2015 geïmplementeerd en geëvalueerd.

### Box 2 De PatientTIME interventie

Om patiënten met lymfklierkanker te ondersteunen met medische gesprekken, hebben we in nauwe samenwerking met patiënten de 'PatientTIME' website ontwikkeld. PatientTIME is een website met informatie en advies ter voorbereiding op gesprekken met artsen en verpleegkundigen. De website bevat videofragmenten van gesimuleerde consulten. De fragmenten gaan over de barrières die patiënten hebben aangegeven te ervaren in de communicatie. De informatie die een deelnemer via de website te zien krijgt is afgestemd op zijn of haar persoonlijke situatie. Patiënten kunnen de website thuis gebruiken om hun consult voor te bereiden.

## Ervaringen van patiënten (hoofdstuk 2)

*Wat helpt en hindert patiënten met lymfklierkanker in de communicatie met zorgverleners?*

In hoofdstuk twee wordt een onderzoek naar de ervaringen van patiënten met medische gesprekken beschreven. Het doel van dit kwalitatieve onderzoek was om in kaart te brengen wat patiënten lastig vinden in gesprekken, maar ook wat hen helpt een gesprek goed te voeren. De toegepaste methode in dit onderzoek is gebaseerd op gestructureerd volgens 'context mapping' en bestond uit twee onderdelen. Eerst werden deelnemers gevraagd thuis een boekje met

*“Meebeslissen,  
vragen stellen,  
mijn wensen  
uitleggen: dat wil  
ik allemaal wel,  
maar ik krijg het  
niet voor elkaar.”*

opdrachten in te vullen over hun ervaringen. Vervolgens werden zij uitgenodigd voor een interview of focusgroep. Op deze manier hebben we data verzameld bij 28 patiënten en 9 partners van patiënten.

De geanalyseerde data resulteerde in een lijst met belemmerende en faciliterende factoren die patiënten tijdens gesprekken met zorgverleners ervaren. Volgens de deelnemende patiënten werd de effectiviteit van de communicatie beïnvloed door hun persoonlijke kenmerken (zoals het omgaan met emoties, kennis, vaardigheden), de kenmerken van de zorgverlener en externe factoren (bijvoorbeeld de tijdsdruk tijdens een consult). Ook identificeerden we drie verschillende 'communicatiefases die patiënten lijken te ervaren: i) een overweldigde, passieve fase, ii) een proactieve, gemotiveerde fase en iii) een bekwame, gevorderde fase. In de verschillende fases lijken patiënten verschillende communicatie barrières te ervaren.

De bevindingen van deze studie kunnen zorgverleners helpen informatie en ondersteuning, die gegeven wordt tijdens een consult, op de patiënt af te stemmen en communicatiebarrières helpen te verwijderen. Daarnaast kunnen de resultaten gebruikt worden voor het ontwikkelen van communicatie-interventies met als doel patiënten te ondersteunen in het bereiken van effectieve communicatie.

## Participatief ontwikkelen (hoofdstuk 3)

*Hoe kunnen we (ernstig zieke) patiënten betrekken bij de ontwikkeling, evaluatie en implementatie van een patiëntgerichte communicatie interventie?*

*“Iedereen om je heen is opeens expert, maar ik ben degene die in de spreekkamer het gesprek moet voeren.”*

Hoofdstuk drie beschrijft het protocol dat toegepast is om de online interventie PatientTIME te ontwikkelen, evalueren en implementeren. Het protocol is gestructureerd volgens het 'Intervention Mapping Framework'. Dit raamwerk gaat uit van een stapsgewijze ontwikkeling, evaluatie en implementatie, waarbij gebruik wordt gemaakt van evidence based principes. De focus in dit hoofdstuk ligt op de manier waarop patiënten zijn betrokken in dit proces. Een veel voorkomend probleem bij het evalueren van online interventies is de hoge

drop-out (uitval van deelnemers) en het zogenaamde non-usage (wel mee doen met de evaluatie, maar niet de website gebruiken). Ongeacht of de interventie effectief is gebleken, blijven na de evaluatie veel interventies op de plank liggen of valt het

gebruik na implementatie tegen. De marginale betrokkenheid van belanghebbenden (waaronder de eindgebruikers) wordt als mogelijke reden genoemd voor deze tegenvallende cijfers. We hebben daarom geprobeerd (ex-)patiënten en hun naasten op verschillende niveaus en met verschillende methodes te betrekken. Het daartoe opgesteld protocol, samengesteld uit verschillende methodes, heeft er voor gezorgd dat patiënten vanaf begin tot eind betrokken zijn geweest in de rol van bijvoorbeeld onderzoekspartner, adviseur, informatieverstrekker of proefpersoon. Voorwaarden voor intensieve samenwerking met (ernstig) zieke patiënten bleken het afstemmen van hun betrokkenheid in de startfase van het project en flexibiliteit in de planning en onderzoeksopzet.

## Communicatiestrategieën modelleren (hoofdstuk 4)

*Is de context van de ontwikkelde videofragmenten niet te overweldigend en worden de communicatiestrategieën onthouden zoals we bedoeld hebben?*

Als onderdeel van het PatientTIME project, hebben we 58 korte videofragmenten ontwikkeld. In deze fragmenten vertellen vijf verschillende patiënten die een vorm van lymfklierkanker hebben (gehad) hun verhaal. Daarnaast worden in de fragmenten verschillende communicatiestrategieën gemodelleerd.

Hoofdstuk vier beschrijft het experiment dat we uitgevoerd hebben om te achterhalen of de emotionele context van de verhalen niet te overweldigend is. Enige spanning (arousal) naar aanleiding van het kijken naar de fragmenten is acceptabel. Dit kan de alertheid verhogen wat de leercapaciteit ten goede komt. Teveel spanning kan echter leiden tot distress, wat we willen voorkomen bij een interventie die thuis (zonder bijzijn van professionals) gebruikt zou worden. Daarnaast wilden we weten of de hoofdboodschap (de verschillende communicatiestrategieën) uit de fragmenten goed overkwam.

*“Wij kwamen vaak thuis, met onbeantwoorde vragen.”*

In het experiment kreeg elke deelnemer drie videofragmenten te zien. Of een deelnemer emotioneel overweldigd werd door de video, hebben we op twee manieren gemeten. We hebben met een gevalideerde vragenlijst de gemoedstoestand van de deelnemer voor en na het experiment gemeten. Hiermee kun je mogelijke bewuste emoties in kaart brengen. Daarnaast hebben we de hartslag en huidgeleiding van de deelnemers tijdens het experiment continu gemeten. Hiermee kun je een mogelijke onbewuste emotie in kaart brengen. Na het

zien van de fragmenten vroegen we de deelnemer naar de boodschap uit de fragmenten.

*“Je weet soms helemaal niet wat je moet vragen.”*

In totaal hebben 75 mensen deelgenomen aan het experiment. Uit de vragenlijst kwam niet naar voren dat deelnemers geëmotioneerd raakten door de videofragmenten. In de fysiologische data (hartslag en huidgeleiding) zagen we kleine veranderingen, maar niet in een mate die duidde op sterke emotionele spanning. Deelnemers konden de hoofdboodschappen uit de verschillende clips goed navertellen. We verwachten daarom dat de emotionele context van de videofragmenten de beoogde informatieoverdracht niet in de weg staat.

## Audio-opnames van consulten (hoofdstuk 5)

*Wat zijn de ervaringen van oncologische zorgverleners met audio-opnames van consulten?*

Uit eerder onderzoek blijkt dat patiënten het vaak prettig vinden hun medisch consult terug te kunnen luisteren. Daarnaast kan het terugluisteren helpen om bijvoorbeeld een duidelijker beeld te krijgen van de behandelingsopties, meer te participeren in vervolgsconsulten en het kan ondersteunen in het proces van keuzes maken en bij therapietrouw. Het opnemen van een consult kan gefaciliteerd worden door het ziekenhuis, maar tegenwoordig kan een patiënt met een smartphone of tablet het consult eenvoudig zelf opnemen. Een onderdeel van het PatientTIME project was onderzoeken wat patiënten er van vinden om het initiatief te nemen hun eigen consult op te nemen.

In hoofdstuk vijf wordt de andere kant van het verhaal belicht. We beschrijven hierin de studie die we hebben uitgevoerd om de ervaringen van zorgverleners met de opnames in kaart te brengen. In totaal hebben 215 Nederlands oncologische zorgverleners (123 artsen en 92 verpleegkundigen) een vragenlijst hierover ingevuld. De meerderheid van de respondenten had ervaring met audio-opnames van consulten; de meesten via een patiënt die met het verzoek kwam het consult op te nemen. De meeste zorgverleners gaven aan hieraan mee te werken. Toch bestaan er veel zorgen rondom de opnames die patiënten zelf maken.

Een belangrijke zorg hangt samen met het gevoel geen controle te hebben over wat er met de opnames gebeurt, en aan de angst voor misbruik van de opnames (bijvoorbeeld via social media). Een zorg van een andere orde is dat respondenten

aangaven bang te zijn dat de opnames verwarrend zijn voor patiënten, en dat het de kans vergroot dat informatie verkeerd geïnterpreteerd wordt. Daarnaast leven er zorgen over het effect van de opnames op het communicatieproces. Zo gaven sommige respondenten aan het gevoel te hebben anders te gaan communiceren omdat het gesprek opgenomen wordt. Tot slot blijkt ook een hoop onduidelijk te zijn over de juridische status van de opnames. Voor een aanzienlijke groep respondenten zijn deze zorgen reden om niet mee te werken met het opnemen van consulten.

Verwacht wordt dat patiënten steeds vaker een medisch consult zullen willen opnemen. Het is daarom van belang de bestaande zorgen die er bij zorgverleners zijn weg te nemen. Daarnaast zouden handvatten geboden kunnen worden over hoe zorgverleners om kunnen gaan met de verzoeken en/ of hoe er goede afspraken gemaakt kunnen worden over de opnames. Tot slot is het van belang duidelijkheid te geven over de juridische status van de opnames.

## Gezien door de ogen van patiënten (hoofdstuk 6)

*Wat zijn de voorkeuren van patiënten met betrekking tot de communicatie van hun zorgverlener, en hoe ervaren ze het communicatieproces tijdens een hematologisch consult?*

Zoals eerder besproken is effectieve communicatie van groot belang voor het kunnen leveren van goede zorg. Effectieve communicatie wordt onder andere gelinkt aan verbeterde fysieke en mentale uitkomsten, verbeterde therapietrouw, hogere kwaliteit van leven en hogere ervaren kwaliteit van zorg.

Eerder onderzoek (o.a. hoofdstuk 2) laat echter zien dat (hematologie) patiënten barrières ervaren in het effectief voeren van medische gesprekken.

Om beter inzicht te krijgen in hoe communicatie binnen de hematologie verbeterd kan worden, hebben we patiënten vooraf aan hun consult gevraagd naar hun voorkeuren met betrekking tot het communicatieve gedrag van hun zorgverlener. Na het consult hebben we gevraagd hoe de patiënten het gesprek hebben ervaren. Uit 78 datasets bleek dat patiënten zowel affectieve als instrumentele vormen van communicatie belangrijk vonden. In de ogen van de patiënt, sloot het affectieve communicatiegedrag van de zorgverlener goed aan bij hun behoefte. In het instrumentele communicatiedomein vonden we meer discrepanties en werd minder aan de behoefte van de patiënt voldaan. Daarnaast hebben we in deze studie

*“Welke informatie zou de arts van mij nodig hebben?”*

gekeken of de resultaten werden beïnvloed door toegang tot de PatientTIME interventie. Het bekijken van videofragmenten van arts-patiënt consulten zou als

*“Ik had geen idee  
wat me te wachten  
stond.”*

‘neveneffect’ kunnen hebben dat het de verwachting over een consult beïnvloedt. De invloed van PatientTIME bleek in deze studie echter geen invloed te hebben op de resultaten.

Om de communicatie in hematologische consulten verder te verbeteren, zouden zorgverleners de verwachtingen van een patiënt kunnen inventariseren bij aanvang van het consult. In het bijzonder met betrekking tot het uitwisselen van informatie en advies. Tegelijkertijd zouden patiënten ondersteund moeten worden in het uiten van hun voorkeuren bij aanvang van een consult.

## Geïntegreerde proces- en uitkomstevaluatie (hoofdstuk 7)

*Wat hebben patiënten aan de interventie?*

In de studie beschreven in hoofdstuk 7 hebben we geëvalueerd of, en zo ja, op welke manier patiënten baat hebben bij de PatientTIME interventie. De interventie bestond uit een website die patiënten vooraf aan hun consult met de zorgverlener konden raadplegen. Voor en na het consult kregen deelnemers een vragenlijst. Deelnemers konden (maximaal) drie consulten meedoen en na afloop hebben we hen een afsluitende vragenlijst voorgelegd.

De interventie werd getest in een gesloten gerandomiseerde trial. Volgens de leidraad van de ‘Medical Research Council’ hebben we eerst een procesevaluatie uitgevoerd. Deze evaluatie is erop gericht hoe de interventie verspreid en opgepakt is en hoe de website gebruikt werd. Vervolgens hebben we geëvalueerd of patiënten die toegang hadden tot de website, meer vertrouwen kregen in het communiceren met hun zorgverlener. Dit hebben we gemeten met een gevalideerde vragenlijst.

*“De arts vertelt me  
zo weinig.”*

In totaal hebben 146 patiënten zich geregistreerd voor de studie. Van hen zijn er 97 gerandomiseerd over de controle- en de interventiegroep. Na de evaluatie konden 87 datasets (90%) geanalyseerd worden.

Ruim de helft van de deelnemers die toegang had tot de interventie (groep b en c) gaf aan dat de website hen hielp in de voorbereiding op het consult. Ze gaven aan dat de website hen bewust maakte van het belang van goede communicatie, en dat het hun communicatievaardigheden ondersteunde. Deelnemers die zich niet

geholpen voelden door de website, gaven als reden aan dat ze al goede communicatievaardigheden en/of al goede gesprekken met hun arts hadden. Zowel in de controle- als in de interventiegroep kregen deelnemers meer vertrouwen in het communiceren met hun zorgverlener. Bij de interventiegroep was dit verschil significant, bij de controlegroep niet. Omdat het interactie-effect niet significant was, kunnen we naar aanleiding van deze studie niet concluderen dat gebruik van de website het vertrouwen in medische communicatie vergroot.

*“Ik wil niet dat de spanning elke keer de overhand krijgt in een gesprek.”*

## Discussie (hoofdstuk 8)

In hoofdstuk acht wordt een samenvatting van de bevindingen gegeven en reflecteren we op de toegepaste interventie, methodes en gevonden resultaten. Gerelateerd aan de interventie worden de voor- en nadelen besproken van de verschillende strategieën die zijn opgenomen in de interventie. We gaan in op het ‘op-maat’ aanbieden van videofragmenten, het opnemen van een consult op audio en het opstellen van een vragenlijst vooraf aan een consult. Ook bespreken we in het kader van het verbeteren van arts-patiënt communicatie, onze keuze om te focussen op patiënten. Daarnaast gaan we in op onze keuze een eHealth interventie te ontwikkelen en bespreken we de voor- en nadelen van het Internet als medium in deze context.

Gerelateerd aan de toegepaste methodes bespreken we de uitdagingen die komen kijken bij het ontwikkelen, evalueren en implementeren van een eHealth interventie. We gaan in op het betrekken van (ernstig) zieke patiënten bij deze processen en de keuze om met een gerandomiseerde trial de interventie te evalueren.



## *Het einde ...*

*De evaluatie van PatientTIME wordt in 2016 afgerond. De inhoud van de interventie wordt overgedragen aan patiëntenorganisatie Hematon. In het najaar van 2016 zal alle informatie via hun website toegankelijk worden. De organisatie zal in die periode speciale aandacht schenken aan het belang van goede communicatie tussen patiënten en zorgverleners.*

*Voortbouwend op de geleerde lessen uit het PatientTIME project heeft het NIVEL een vervolgproject opgestart onder de naam 'Luistertijd'. Dit project is specifiek gericht op het ondersteunen van oudere patiënten met kanker en hun zorgverleners.*

*Daarnaast zouden we in de lijn van het PatientTIME project graag verder willen met het ondersteunen van patiënten die te maken krijgen met acute vormen van kanker. In de vaak hectische diagnostische fase worden zowel arts als patiënt communicatief uitgedaagd met lastige keuzes die snel genomen moeten worden en waarvan de consequenties soms moeilijk te overzien zijn. Er liggen nog vele uitdagingen te wachten in dit vakgebied. 'Het einde' van dit proefschrift dus, maar niet het einde van onze zoektocht naar wegen om patiënten op een effectieve manier te kunnen ondersteunen in hun gesprekken met zorgverleners en eHealth interventies succesvol te ontwikkelen, evalueren en implementeren.*



Dankwoord

Mijn grote dank gaat uit naar alle **patiënten** die, op welke manier dan ook, betrokken zijn geweest bij PatientTIME. Bedankt voor het delen van jullie kennis en ervaringen, de open gesprekken, tips, kritiek en zelfs de dagboeken die ik van sommigen te lezen kreeg. Het heeft dit werk zoveel rijker gemaakt. Vertegenwoordigers en vrijwilligers van **Hematon** (eerder LVN), het was een voorrecht om met zo'n professionele patiëntenorganisatie te morgen samenwerken. Dank voor jullie medewerking en enthousiasme.

**Sandra**, naast dat je me ontzettend veel hebt geleerd, was het ook erg leuk om met je te mogen samenwerken. Minstens zo belangrijk denk ik. Dankjewel voor het 'risico' dat je nam om mij (als vreemde eend in de bijt) aan te nemen. Dankjewel voor je vertrouwen en voor de vrijheid die je me hebt gegeven. **Evelyn, Josée, Hans** en **Jos**, ook jullie hebben mij geïnspireerd en gemotiveerd. **Evelyn**, op het Radboud kreeg ik een kijkje in de keuken van het communicatieonderwijs in het geneeskunde curriculum. Je enthousiasme hiervoor is aanstekelijk. **Josée**, via jou kwam ik in de kliniek. Met bewondering heb ik mogen observeren hoe je je vak uitvoert. **Hans**, als ervaringsdeskundige hield je het patiëntenbelang in de gaten en lette je scherp op de praktische uitvoerbaarheid van alle stappen. Dit was absoluut onmisbaar in het project. **Jos**, samen dachten we al na over implementatie toen er nog helemaal niets ontwikkeld was. Schermpjes zijn handig, maar naast elkaar brainstormen met wat vellen papier minstens zo. Dank voor jullie tijd en energie, voor alles wat jullie me geleerd hebben.

**Prof. dr. Kremer, Prof. dr. Kersten** en **Prof. dr. Smets**, hartelijk dank voor het beoordelen van mijn proefschrift en voor jullie rol tijdens de verdediging. **Prof. dr. Gemert-Pijnen, Prof. dr. Blijlevens, Prof. dr. ir. Goosens** en **dr. Noordman**, hartelijk dank voor jullie tijd en bereidheid te opponeren. **Prof. dr. Roter** and **Prof. dr. Makoul**, thank you for your support in the setup of this research project.

**Harm-Wouter**, het viel niet mee om als ontwerper het echte 'ontwerpwerk' aan iemand anders over te laten, maar met onze samenwerking kwam het wel goed. Ik weet nu hoe waardevol het is om met een ontwikkelaar te kunnen sparren, die naast zijn programmeer-kunsten veel weet over wetenschappelijk onderzoek; veel dank hiervoor. **Doortje**, van informed consent tot de final touch aan het proefschrift; wat is het gezellig om met jou samen te werken, dankjewel voor alle hulp. **Akke**, bedankt dat je me het eerste jaar wegwijs hebt gemaakt. **Paul** en **Anne-Vicky**, bedankt voor

alle (digitale) hulp en gezelligheid. **Carlijn** en **Leanne**, bedankt voor het coördineren van de vragenlijsten en het oplossen van alle niet-standaard opties die ik er in wilde hebben. **Richard**, **Stefan** en **Jan-Willem**, bedankt voor de hulp bij het regisseren, opnemen en monteren van de films. **Cobi**, **Twan**, **Frank**, **Ine**, **Jacques**, **Gerdie**, **Nienke** en **Suzanne**, bedankt voor het tot leven brengen van de scripts en de leuke draaidagen. Dankjewel **Ilse**, **Lotte** en **Brigit**, jullie enthousiasme resulteerde in belangrijke bijdrages aan dit boek. **PPI** en **WO collega's**, bedankt voor de feedback op concept artikelen. **Leonie**, dank voor je hulp bij het psychofysiologie stuk. Het was een zijstraat van de zijstraten waarin ik me begaf en het was fijn om hierover met jou te kunnen sparren. Communicatie collega's **Mara**, **Ligaya**, **Liesbeth**, **Jeanine** en **Janneke**, dank voor jullie adviezen, support en de gezelligheid tijdens congressen. Kamergenoten **Liana**, **Sara**, **Christel**, **Susan**, **Janneke**, **Hanneke** en **Thamar**; dank voor de gezelligheid rondom de theetafel. En **Arie**, te gek dat je die boksbal op onze kamer hebt gehangen.



Ik zou makkelijk kunnen verdrinken in een groot project als dit. Dankzij fantastische bliksemafleiders en support in de vorm van familie en vrienden is dit niet gebeurd.

**Pepers**, een jaar samen roeien was de start van veel leuks. Ik kijk er altijd naar uit om jullie weer te zien. **Annemarie**, die laatste loodjes; wat een toeval dat we die konden delen. We hadden de afgelopen jaren in ieder geval voldoende PEper in ons r'Eight om deze eindstreep te halen. **Maaïke**, jouw ongeluk deed mij een hoop relativeren, en je doorzettingsvermogen tijdens je revalidatie periode was inspirerend. Wat ben ik blij dat je er bent. **Eef**, ook jij had een inspirerende bak doorzettingsvermogen om te komen waar je nu bent. Ik mis nu onze racefiets ritjes wel! **Rienke**, jouw oppeppers en lummeltips kwamen elke keer precies op het goede moment. Je hebt nooit veel woorden van mij nodig om me door te hebben. Alle zeven; dankjewel voor alle leuke afleiding.

‘Mannen Van De Mooie Plannen’, **Daniel** en **Harm-Wouter**, hoe we tijd-technisch ons Hamburgs avontuur er tussendoor hebben kunnen fietsen...het is me een raadsel. Toch kreeg ik veel energie van het samenwerken met jullie. Wie weet wat er nog meer voorbij gaat komen. Ik kijk er naar uit. **Elma**, wat heerlijk om af en toe bij te

kletsen. **Sieb**, ondanks de ene vraag ... vind je het nog steeds gezellig om af te spreken, gelukkig maar. **Joram** en **Martijn**, we zien elkaar niet zo vaak, maar het is me zoveel waard. Onze Delftse avonturen (van JvB tot rosé-aardappelpuree) vergeet ik nooit. **Martijn**, laten we ons culinaire toertje door Utrecht nog een tijd volhouden. **Floor**, achter jou is het goed stuk gaan, eerst in de boot en nu op de fiets door het bos. Buitenspelen blijft een goed middel om je hoofd leeg te maken. Straks lekker in jullie 'achtertuin'? Hoewel samen relaxen ons toch ook goed afgaat. **Zeeuws-Vlaamse beauty's**; hoewel we al lang zijn uitgevlogen is het altijd een beetje thuiskomen bij jullie. **Marlieke**, ik verdwaalde na het nieuws dat je ging emigreren, maar weet dat onze vriendschap geen last zal hebben van de afstand. Al ga ik onze Utrechtse pauzes wel (voluit) missen. **Mijke**, jij buitenspeelkoningin. Samen surfen, snowboarden, fietsen, walvissen spotten en kamperen; laten we dat nog héél héél lang volhouden (en wie weet ooit de wereld rond zeilen!). **Marleen**, de aanstichtster van dit alles. Zoals je me wel vaker tipt op life changers, deed je dat ook op een andere baan toen ik daar (meer dan) aan toe was. Ik realiseerde het me nog niet direct, maar stond voor een traject waar jij midden in zat. Met jouw tips & tricks (en onze gedeelde liefde voor Felix & friends) heb ik nu ook de eindstreep gehaald. Twee boekjes; dat hadden we niet kunnen verzinnen toen we onze matjes (nu 15 jaar geleden!) naast elkaar legde. Wat fijn dat je straks naast me staat.

**Lieve familie**, dank voor jullie interesse, bijspring-momenten, wijze woorden en gezellige onzin. **GJ** en **Han**, altijd dichtbij en sinds een paar jaar ook letterlijk om de hoek. **Kasper** en **Amanda**, dank voor de leuke crash momentjes na het fietsen. **Opa** en **Oma**, een dag in Sluis gaat altijd te snel voorbij. Het is heerlijk om bij jullie te zijn. **Lydia**, het was fantastisch om samen door Nice te struinen. Je bent altijd ver weg en toch altijd zo dichtbij. Veel dank voor de mooie kافت die je gemaakt hebt. (Schoon)broers en schoonzussen **Ties**, **Emma**, **Stijn**, **Lisanne**, **Thomas** en **Astrid**, wat een mazzel heb ik met jullie. **Ties**, fijn dat je straks naast me wil staan als paralympische bosninf [Nota, 2014]. Met jouw creatieve gedachtegangen ben ik verzekerd van een originele back-up. Dank voor je altijd goede zorgen. **Niek** en **Marlies**, al bijna 15 jaar mag ik bij jullie over de vloer komen, en dat voelt als een warm thuis, dankjewel. **Papa** en **Mama**, al duizenden patiënten hebben jullie behandeld en er heeft er nog nooit eentje een woord gezegd...jullie hadden dit onderwerp vast ook niet zien aankomen. Dank voor de fijne basis waaruit wij onze eigen weg konden gaan en het warme nest dat jullie nog steeds voor ons zijn.

Lieve **Liv** en Lieve **Sven**, samen dansen door de kamer, zwemmen als dolfijnen, kamperen aan het strand, hollen over de hei, zeilen naar 'de overkant' van de wereld: jullie kunnen er wat van als kleine bliksemafleiders. Ik kijk uit naar wat we nog meer gaan beleven.

Lieve **Gert**, voor alles. Die woorden dekken de lading, maar zijn ook een beetje saai. En met jou samen leven is alles behalve saai. Afgelopen jaren was dit het enige project dat niet veranderde in ons vaak chaotische leventje. Vanaf het lastige begin, tussen de boot- en baanwissels door, tijdens het reizen, verhuizen, verbouwen, tot aan de laatste loodjes; jij was mijn rots en jij gaf mij de ruimte. Tja, en met die oneindige lijst van plannen en dromen kunnen we nog wel zeven levens vullen. Als ik ze dan maar wel alle zeven samen met jou mag leven.

(en de Cat Empire, en Lindt).



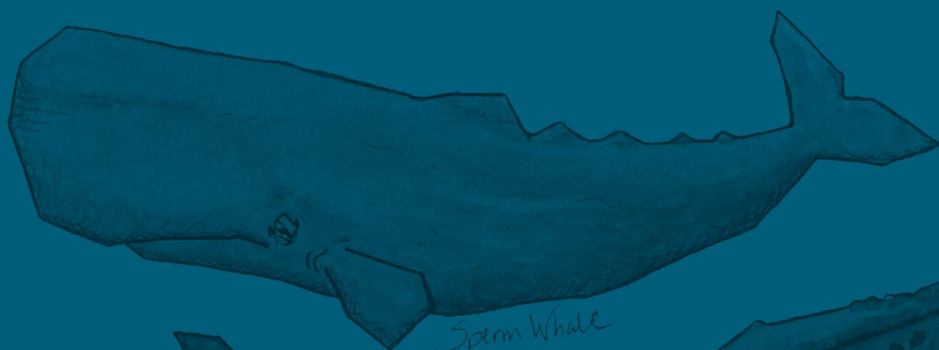


## About the author

Inge Renske van Bruinessen was born on March 10th 1983 and grew up in Aardenburg, the Netherlands. In 2001 she graduated from high school at 't Zwin College in Oostburg. She went on to study Industrial Design Engineering (IDE) at Delft University of Technology (DUT) and (for six months) at the University of Technology Sydney.

After obtaining her bachelor degree engineering, she followed the master Integrated Product Design at DUT. A specialization in Medisign followed; a program focused on designing medical applications that meet the needs of health care professionals and patients, and to solve problems in human-product interaction. After an internship at Draeger Medical, where she developed mobile ventilation equipment for the scheduled transport of critically ill patients, she obtained her Master of Science degree (February 2009).

Subsequently, she started working at the Delft Centre of Entrepreneurship and developed projects and courses for the “health, innovation and entrepreneurship” domain at DUT. In February 2011, Inge started as a researcher under supervision of Prof. Dr. S. van Dulmen on a project funded by the Dutch Cancer Society. She defends her PhD thesis on this project in October 2016. Inge continues working on participatory research, development and implementation projects for (e)healthcare and she started woodworking classes for a change of thoughts.



Sperm Whale



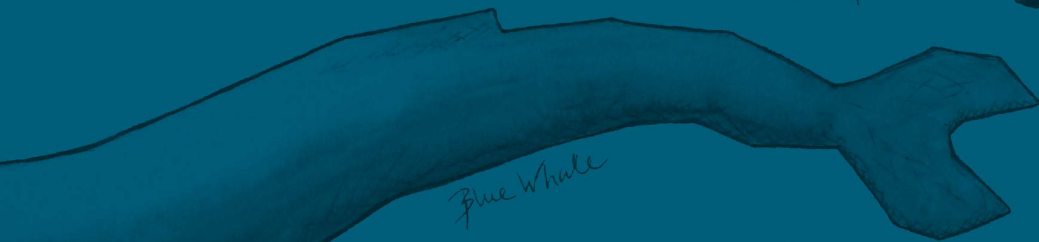
Humpback Whale



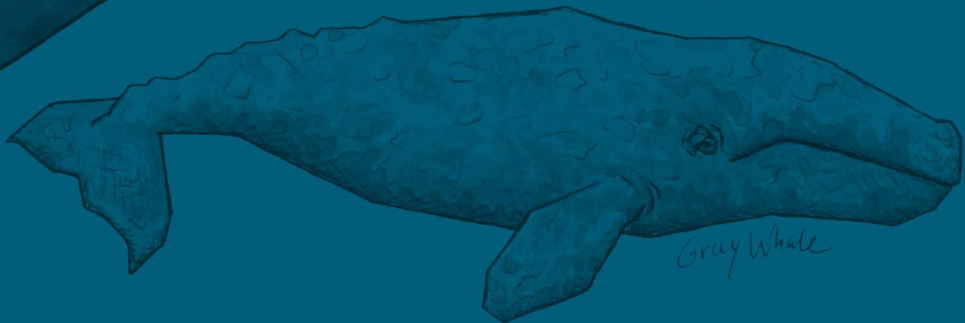
Right Whale



Killer Whale



Blue Whale



Gray Whale

